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Supreme Court, U.S.
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In The
Supreme Court of the United States

ALBERTSON'S, INC., *et al.*,

Petitioners,

v.

JENNIFER KANTER, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The California Supreme Court

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Seventy years ago, Congress decided that "all . . . proceedings for the enforcement, or to restrain violations, of [the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act")] shall be by and in the name of the United States." 21 U.S.C. § 337(a). In 1990 amendments to the FDCA, Congress created a narrow, secondary enforcement role for state governments. It allowed states to enact laws identical to specified portions of the FDCA, *id.*, § 343-1, and also permitted state governments to enforce certain FDCA provisions in federal court under certain conditions, *id.*, § 337(b). Congress, however, has never permitted the private enforcement of FDCA requirements. The California Supreme Court nonetheless held that Respondents, private plaintiffs, could bring a class action to enforce the FDCA under the aegis of state law.

The question presented is: Are private parties' state law claims to enforce FDCA requirements preempted by Congress' mandate that the Act be enforced only by the federal or state governments?

PARTIES TO THE PROCEEDING

Petitioners are Albertson's, Inc., Safeway Inc., The Kroger Co., T.A.C.T. Holding, Inc., Trader Joe's Company, Bristol Farms, Inc., Ocean Beauty Seafoods, Inc., Whole Foods Market California, Inc., and Mrs. Gooch's Natural Foods Market, Inc.

Respondents are Jennifer Kanter, Ben Betts, Ellyn Gerson, David Matsumoto, Lyta Jocum, Julian Carroll, Arleen Rovere, Monique Gauthier, Ivania Lourdes Flores, Sheila Malone, Pastor Romney Bernadette Darkin, and Cesar Tercero Alonzo.

RULE 29.6 STATEMENT

SUPERVALU INC., a publicly traded company, is the parent and owns the stock of New Albertson's, Inc. which consists of the core supermarket businesses owned by Albertson's, Inc. at the time this lawsuit was filed. New Albertsons, Inc. is an active corporation and a wholly owned subsidiary of SUPERVALU INC. No publicly held company owns 10% or more of the stock of SUPERVALU INC.

SUPERVALU INC. is also the parent and owns the stock of New Bristol Farms, Inc., which consists of the core supermarket businesses owned by Bristol Farms, Inc. at the time this lawsuit was filed. When New Bristol Farms, Inc. was an active corporation, it was a wholly owned subsidiary of SUPERVALU INC. SUPERVALU INC. is currently the parent and owns the stock of Bristol Farms, Inc.

RULE 29.6 STATEMENT – Continued

Safeway Inc. ("Safeway") is a publicly traded company. AXA Assurances I.A.R.D. Mutuelle (a French mutual insurance company), AXA Assurances Vie Mutuelle (a French mutual insurance company), AXA Courtage Assurance Mutuelle (a French mutual insurance company, and along with the first two acting as a parent holding company), AXA (a French company and parent holding company), and AXA Financial, Inc. (a Delaware corporation and parent holding company) beneficially owned 77,820,579 shares of Safeway common stock as of August 31, 2007, representing 17.7% of Safeway's outstanding shares. AllianceBernstein L.P. (a subsidiary of AXA Financial, Inc. organized under the laws of the State of Delaware) is deemed to have sole dispositive power over 77,258,207 of those shares.

The Kroger Co. is a publicly traded company. No publicly held company owns 10% or more of its stock.

Trader Joe's Company is owned entirely by T.A.C.T. Holding, Inc., a privately held company. There are no parent corporations of T.A.C.T. Holding, Inc. and no publicly held company owns more than 10% of T.A.C.T. Holding, Inc.

Mrs. Gooch's Natural Foods Market, Inc. and Whole Foods Market California, Inc. are 100% wholly owned subsidiaries of Whole Foods Market, Inc., which is a publicly traded company. No publicly held company owns 10% or more of its stock.

RULE 29.6 STATEMENT – Continued

Ocean Beauty Seafoods LLC is an Alaska limited liability company owned 50% by Ocean Beauty Holdings, Inc., a Washington corporation formerly known as Ocean Beauty Seafoods, Inc., and 50% by Bristol Bay Economic Development Corporation, an Alaska nonprofit corporation.

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OPINIONS BELOW

The opinion of the California Supreme Court (Pet. App. 1) is reported at 42 Cal. 4th 1077, 175 P.3d 1170 (2008). The opinion of the California Court of Appeal (Pet. App. 36) is reported at 142 Cal. App. 4th 805 (2006). The opinion of the trial court (Pet. App. 51) is unreported.

JURISDICTION

The opinion of the California Supreme Court was issued on February 11, 2008. (Pet. App. 1.) The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1257.

STATUTORY PROVISIONS INVOLVED

The FDCA provides, in relevant part:

> (a) Except as provided under subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. . . . .
>
> (b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is

the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1) –

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

21 U.S.C. § 337.

The FDCA further provides, in relevant part:

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce –

. . . .

(3) any requirement for the labeling of food of the type required by section

> 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section. . . .

21 U.S.C. § 343-1(a)(3).

STATEMENT OF THE CASE

This case concerns whether FDCA requirements will be enforced exclusively by the federal and state governments, or by private parties as well. When Congress enacted the FDCA in 1938, it deliberately and consciously rejected the possibility of private enforcement in favor of exclusive federal enforcement. When Congress amended the Act in 1990, it carved out a limited exception to exclusive federal enforcement, allowing state governments to enforce certain FDCA violations under specified conditions. Congress, however, never altered its long-standing prohibition against private enforcement actions.

The California Supreme Court nevertheless held that Respondents, private plaintiffs, are entitled to enforce FDCA requirements governing the use of artificial color in farm-raised salmon under identical state laws. Its decision cannot be reconciled with Congress' government enforcement scheme, or with the decisions of this Court and many lower courts reinforcing the Congressional ban on private FDCA enforcement.

A. The Federal Statutory Scheme

1. Congress' Original Plan Mandated Exclusive Federal Enforcement and Unequivocally Prohibited Private Enforcement.

From its inception in 1938, the FDCA was intended to be enforced by the federal government – and not by private parties. In fact, Congress considered and rejected a version of the statute that would have allowed a private right of action. *National Women's Health Network, Inc. v. A. H. Robins Co.*, 545 F. Supp. 1177, 1179-80 (D. Mass. 1982) (citing Hearings on S. 1944 (Subcommittee of Committee on Commerce 73d Cong., 2d Sess. (1933)). It opted instead for a provision mandating that "all" proceedings "for the enforcement, or to restrain violations" of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337.

In keeping with its plan of exclusive federal enforcement, Congress afforded the Food and Drug Administration ("FDA"), the responsible federal agency, a wide range of enforcement options. It authorized the FDA to bring civil actions to seize misbranded or adulterated goods, to restrain violations of the FDCA, and to seek civil and criminal penalties for such violations. 21 U.S.C. §§ 332-334.

As part of its careful design, Congress also gave the FDA the power *not* to prosecute "minor violations of [the Act] whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336. Congress

thus ensured that the federal government would decide whether and how to enforce the law.

Courts interpreting the FDCA's enforcement framework before it was amended in 1990 held that Congress had deliberately excluded private claims by placing enforcement exclusively in the hands of the federal government, *see, e.g.*, *Pacific Trading Co. v. Wilson & Co., Inc.*, 547 F.2d 367, 370 (7th Cir. 1976) ("[T]he statute does not provide a cause of action for private parties suing for civil damages."), even those claims brought under state law, *see, e.g.*, *National Women's Health*, 545 F. Supp. at 1181 (holding that a private right of action to enforce FDCA standards is "inconsistent with the federal regulatory scheme, whether the right is based in federal or state law"); *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass. 1986) (same).

2. Congress' 1990 Amendments Created A Limited Role For State Governments, But None For Private Parties.

Cognizant of the uniform case law prohibiting private enforcement, Congress enacted the Nutrition Labeling and Education Act of 1990 ("NLEA"), which amended the FDCA to require nutrition labeling on certain foods and to permit state government enforcement of specified labeling requirements. Two provisions of the NLEA pertain to the state enforcement of

federal labeling requirements: sections 343-1 and 337(b).

Section 343-1 allows states to enact laws with requirements "identical" to certain FDCA labeling requirements. 21 U.S.C. § 343-1. One of the FDCA provisions that section 343-1 permits states to replicate is section 343(k), the provision on which Respondents' claims are based, which deems any food containing artificial coloring to be misbranded "unless it bears labeling stating that fact," *id.*, § 343(k). Although section 343-1 is silent on the issue of enforcement, the House Report indicates that state laws enacted pursuant to section 343-1 may only be enforced by "governmental entities":

> The bill . . . contains a provision that would prevent State and local governments from adopting inconsistent requirements with respect to the labeling of nutrients or with respect to the claims that may be made about the nutrients in foods. However, these *governmental entities are explicitly permitted to enforce Federal requirements with respect to nutrition labeling.*

(Pet. App. 74 (H.R. Rep. No. 101-538, 2d Sess., p. 8 (1990) (emphasis added)).)

The other amendment was the addition of section 337(b) to the original section 337 (which was renumbered as section 337(a)). It carved out a narrow exception to exclusive federal enforcement, but only for state governments. Section 337(b) permits state

governments to enforce certain sections of the FDCA in federal court after giving the FDA notice and the opportunity to preempt any state government action with an action of its own. 21 U.S.C. § 337(b).

Together, sections 337(b) and 343-1 were intended to give states the option of enforcing federal labeling requirements under the mantle of federal or state law, in either federal or state court. Under section 337, "[a] State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of" the FDCA in federal court. (21 U.S.C. § 337(b)(1); Pet. App. 75 (H.R. Rep. No. 101-538, 101st Cong., 2d Sess., p. 23 (1990) ("The proceedings [under section 337(b)] would be brought in Federal court and would supplement the FDA's enforcement capabilities.")).) Under section 343-1, states can enforce those same FDCA requirements under identical state law in state court. As Representative Henry Waxman, who originally introduced the bill in the House, explained:

> *H.R. 3562 recognizes the importance of the State role*: by allowing *States* to adopt standards that are identical to the Federal standard, which may be enforced in State court; by allowing the *States* to enforce the Federal standard in Federal court.

(Pet. App. 70 (House Debate on H.R. No. 3562, 101st Cong., 2d Sess., 136 Cong. Rec. 1539 (daily ed. July 30, 1990) (emphasis added)).) By way of both sections 337(b) and 343-1, the NLEA allowed state enforcement of certain federal labeling requirements, but

never granted private parties any enforcement rights whatsoever.

B. Procedural History

Respondents brought this class action claiming that Petitioner supermarkets violated FDCA section 343(k) and its implementing regulations by failing to disclose that farm-raised salmon they sold contained artificial coloring. (JA 162-64 (Consolidated Amended Class Action and Representative Action Complaint ("Complaint")).) Although claims are stated under numerous state laws, including the Unfair Competition Law ("UCL"), Cal. Bus. and Prof. Code § 17200 *et seq.*, the Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750 *et seq.*, and the False and Misleading Advertising Law, Cal. Bus. and Prof. Code § 17500, the predicate for each claim is identical: the violation of FDA regulations and "equivalent provisions of California law" governing the use of color additives in farm-raised salmon.[1] (JA 169-72 (Complaint).)

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[1] California's UCL proscribes any "unlawful business activity," which includes "anything that can properly be called a business practice and that at the same time is forbidden by law." *Barquis v. Merchants Collection Assn.*, 7 Cal. 3d 94, 113 (1972). Respondents' UCL claims are predicated on violations of the color additive provisions of California's Health and Safety Code – provisions that replicate the FDA's color additive regulations *in toto*, *see* Cal. Health & Saf. Code § 110090. When the California Legislature enacted its "little FDCA," called the Sherman Law, it did not include an express private right of action. *See id.*, § 111840.

Respondents seek restitution, compensatory damages, and an injunction "to permanently halt [Petitioners'] misbranding" in violation of federal and identical state law. (JA 172-73.)

1. The Trial Court's Decision Dismissing Respondents' Case On Federal Preemption Grounds

Petitioners demurred to Respondents' Complaint on federal preemption grounds, arguing that Respondents' claims – all of which are based on violations of the FDCA and its implementing regulations – are barred by the FDCA's express prohibition on private rights of action. (JA 193-241.)

The trial court sustained Petitioners' demurrer and dismissed Respondents' case in its entirety. (Pet. App. 64.) It recognized that Respondents' Complaint does not allege any wrongful conduct beyond the federal violations, and that "[r]esolving [Respondents'] claims will have to turn on [Petitioners'] compliance with the FDA's regulations." (Pet. App. 58.) The trial court concluded that a private state law action that "seeks to borrow FDCA standards is barred by § 337(a) of the FDCA." (Pet. App. 55.)

2. The California Court Of Appeal's Decision Unanimously Affirming The Trial Court's Dismissal On Federal Preemption Grounds

In a published decision, the Court of Appeal unanimously affirmed the trial court's federal preemption decision. (Pet. App. 36.) Relying on this Court's opinion in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court of Appeal held that FDCA section 337 "precludes a private right of action to enforce the FDCA." (Pet. App. 45.) It reasoned that "[b]y providing that only the federal government and, in some limited circumstances and only after giving notice to the federal government, a state may commence an action to enforce the FDCA, *Congress reserved for the federal government and the states the discretion to enforce or not enforce the FDCA in any particular set of circumstances and afforded the federal government a degree of oversight of the enforcement of the act.*" (Pet. App. 46-47 (emphasis added).)

The Court of Appeal concluded:

> To allow a private person to prosecute a state law private right of action *based on a violation of the FDCA* would interfere with that governmental prosecutorial discretion and federal government oversight and conflict with the clear congressional intent to provide for a comprehensive and exclusive governmental enforcement scheme.

(Pet. App. 47 (original emphasis).) Because all of Respondents' claims are admittedly "based on a violation of the FDCA," the Court of Appeal held that allowing private parties to pursue them would "frustrate the purposes of exclusive federal and state governmental prosecution of the act." (Pet. App. 37-38.) It affirmed the trial court's dismissal on the ground that "section 337(a) impliedly preempts all of [Respondents'] causes of action." (Pet. App. 38.)

3. The California Supreme Court's Decision Allowing Respondents' Private FDCA Claims To Proceed.

The California Supreme Court reversed. (Pet. App. 35.) Its decision begins and ends with the "strong presumption against preemption" (Pet. App. 12, 35), which it applied with "particular force" because consumer protection laws and laws regulating the proper marketing of food "are within the states' historic police powers" (Pet. App. 13).

The court held that Respondents' claims were not preempted because they had sued not under the FDCA itself, but rather under state laws identical to federal standards – laws that FDCA section 343-1 authorized states to enact. (Pet. App. 24.) Acknowledging that Congress "said absolutely nothing" about the private enforcement of such identical state laws (Pet. App. 18), the court nevertheless presumed that Congress "made a conscious choice" not to "preclude

states from providing private remedies for violations of those laws" (Pet. App. 34, 19).

The California Supreme Court further held that section 337 is not a valid source of preemption because Respondents' claims "arise out of violations of [identical state law], not out of the FDCA itself." (Pet. App. 31.) It distinguished, for example, a case in which "the complaint alleged defendant violated the FDCA, misbranded its food in violation of federal regulations, and made actionable health claims in violation of federal regulations." (Pet. App. 32 (discussing *Fraker v. KFC Corp.*, No. 06-CV-01284, 2007 WL 1296571 (S.D. Cal. Apr. 30, 2007)).) The California Supreme Court did not discuss Respondents' allegations that Petitioners violated the FDCA and misbranded their salmon in violation of FDA regulations (JA 163-64) – allegations that serve as the factual predicate for all of their state causes of action (JA 169-72).

REASONS FOR GRANTING THE PETITION

At stake in this case is whether the FDCA will continue to be enforced by government entities – as it has been for seventy years – or whether the door is now open to private class action attorneys to decide whether and how to enforce the federal Act. The California Supreme Court's decision approving Respondents' private FDCA enforcement claims thwarts Congress' exclusively public enforcement plan and

conflicts with this Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001), which recognizes the Congressional prohibition against private FDCA enforcement actions.

The California Supreme Court's decision is also an open invitation to private plaintiffs nationwide to bring class actions alleging FDCA violations. The decision below will wreck Congress' exclusive government enforcement scheme and all its built-in advantages. Because of the broad jurisprudential and practical significance of the ruling below on federal enforcement of the FDCA, Petitioners respectfully request that this Court obtain and consider the views of the Solicitor General before deciding whether to grant review.

I. THE CALIFORNIA SUPREME COURT'S DECISION CONFLICTS WITH CONGRESS' PROHIBITION AGAINST PRIVATE FDCA ENFORCEMENT ACTIONS AND THIS COURT'S DECISION IN *BUCKMAN* UPHOLDING THAT PROHIBITION.

A. FDCA Section 337 Reflects Congress' Unmistakable Intent To Preclude *All* Private Enforcement Actions, As This Court And Many Lower Courts Have Recognized.

Section 337 of the original FDCA mandated that only the federal government could enforce the Act, 21 U.S.C. § 337(a), and all courts interpreting section

337 before it was amended in 1990 understood that Congress had erected a barrier against private rights of action, whether grounded in federal or state law, *see, e.g.*, *Pacific Trading*, 547 F.2d at 370; *National Women's Health*, 545 F. Supp. at 1181; *Animal Legal Defense Fund*, 626 F. Supp. at 283. When Congress amended section 337 in 1990 to allow certain limited actions by state governments, it was undoubtedly aware of that uniform case law. *Keene Corp. v. United States*, 508 U.S. 200, 212 (1993) (holding that when Congress reenacts statutory language that has been consistently interpreted by the courts, "the presumption that Congress was aware of the[ ] earlier judicial interpretations and, in effect, adopted them" applies). While Congress expressly decided to authorize state enforcement, it made no change in the proscription of private enforcement under section 337. *Bailey v. Johnson*, 48 F.3d 965, 967 n.1 (6th Cir. 1995) (acknowledging, while dismissing a private cause of action to enforce the FDCA, that when Congress amended section 337 in 1990 to allow for certain enforcement actions by state governments, it "made no change respecting private actions").

This Court thus held in 2001 that "[t]he FDCA leaves no doubt" that "private litigants" cannot bring suits for noncompliance with the FDCA. *Buckman*, 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)).[2]

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[2] Federal appellate courts are in accord. *See, e.g.*, *In re Orthopedic Bone Screw Products Liability Litig.*, 193 F.3d 781, 788 (3d Cir. 1999) ("It is well-settled . . . that the FDCA creates

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Although *Buckman*, this Court's only decision addressing section 337, involved state law fraud-on-the-FDA claims that were preempted for reasons largely unique to those claims, numerous lower courts have recognized that Congress' mandate of no private enforcement extends to state law claims to enforce requirements substantively identical to federal law, *see, e.g.*, *Fraker*, 2007 WL 1296571, at *4 ("[T]o the extent Plaintiff contends that alleged violations of the FDCA and [identical California law] give rise to viable state law claims, such claims are impliedly preempted by the FDCA."); *Summit Tech., Inc. v. High-Line Medical Instruments Co.*, 922 F. Supp. 299, 306, 316 (C.D. Cal. 1996) (dismissing state law claims that did not involve "any additional theories" beyond purported FDCA violations as attempts to "circumvent 21 U.S.C. § 337(a)'s denial of a private right of action"); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 838 (W.D. Tex. 2001) (dismissing on federal preemption grounds state law claims "involv[ing] all the facts and arguments to be determined in a misbranding enforcement action, matters within the sole jurisdiction of the FDA"); *Autin v. Solvay Pharmaceuticals, Inc.*, No. 05-2213, 2006 WL 889423, at *4 (W.D. Tenn. Mar. 31, 2006) (holding that state law claims "based on an alleged violation of

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no private right of action."); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (holding that "no . . . private right of action exists" under the FDCA); *Bailey*, 48 F.3d at 968 ("Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA.").

the FDCA" are preempted by section 337(a)); *Ethex Corp. v. First Horizon Pharmaceutical Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) (dismissing defendant's false advertising counterclaim where the "touchstone" of defendant's argument was an FDCA violation); *Anthony v. Country Life Mfg., L.L.C.*, No. 02C1601, 2002 WL 31269621, at *1 (N.D. Ill. Oct. 9, 2002) (granting defendant's motion to dismiss state consumer fraud claims on the ground that they "amount[ed] to nothing other than an attempt to enforce the FDCA"); *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459, 1997 WL 94237, at *7 (D. Kan. Feb. 26, 1997) (dismissing plaintiff's unfair competition claim on federal preemption grounds when the "crux" of the claim was an FDCA violation).

Although the California Supreme Court sought to distinguish those cases because "[t]hey invariably deal with a party seeking to enforce (sometimes through the use of state law) the FDCA" (Pet. App. 31), that is no less true here. The factual allegations that support Respondents' state law claims are the very same factual allegations that would support an FDCA claim. (JA 153-173.) As the Court of Appeal recognized, the correct litmus test is not whether claims are labeled state or federal, but "what facts the plaintiffs will be required to prove under the allegations of their complaint":

> If those facts demonstrate violations of the FDCA, then preemption will apply irrespective of the particular state law theories of recovery relied upon by the plaintiffs. To hold

> otherwise would sanction a patent evasion of section 337(a) and would permit the plaintiffs to do the very thing that adherence to federal law would preclude.

(Pet. App. 50.) The California Court of Appeal's decision was but the latest in a long line of cases to hold that state law claims "involv[ing] all the facts and arguments to be determined in a misbranding enforcement action" under the FDCA are preempted. *Healthpoint*, 273 F. Supp. 2d at 838.

The California Supreme Court nevertheless insisted that FDCA section 337 "only implicates efforts to enforce *federal* law," and does not "limit, prohibit, or affect private claims predicated on *state* laws." (Pet. App. 29.)[3] Its opinion ignores the fact that when Congress amended section 337 in 1990, it knew that the provision had been consistently interpreted to preclude private actions brought under *both* federal and identical state law. Had Congress actually intended to allow private state law actions, section 343-1 presented the perfect opportunity. While permitting states to enact laws identical to certain FDCA provisions, Congress easily could have told the courts

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[3] Although not cited by the California Supreme Court, two federal district courts earlier reached the same conclusion. *Vermont Pure Holdings, Ltd. v. Nestle Waters North America, Inc.*, No. Civ.A. 03-11465, 2006 WL 839486, at *6 & n.5 (D. Mass. Mar. 28, 2006); *Reyes v. McDonald's Corp.*, Nos. 06 C 1604, 06 C 2813, 2006 WL 3253579, at *6 (N.D. Ill. Nov. 8, 2006). They are discussed below. (*See* section II, *infra*.)

that – contrary to what they had held – private claims to enforce state replicas of FDCA provisions were to be permissible in the future.

Instead, Congress gave no signal that it intended to authorize private enforcement when it enacted an unambiguous, highly detailed provision for state enforcement. It is hard to believe that Congress legislated about enforcement and only changed the law as to state enforcement, but actually intended to permit both state *and* private enforcement, without mentioning private enforcement at all. *See Monessen Southwestern Ry. Co. v. Morgan*, 486 U.S. 330, 336-38 (1988) (where Congress had amended a statute and "dispensed with [certain] doctrines," but had not addressed the specific doctrine at issue, this Court considered "Congress' silence on this matter in the appropriate historical context" and was "unpersuaded that Congress intended to abrogate that doctrine *sub silentio*"). The NLEA's legislative history, which discusses the "importance of the state role" (Pet. App. 70) and refers to enforcement by "governmental entities" (Pet. App. 74), makes the lower court's theory that Congress somehow intended to allow private enforcement without ever mentioning it even more implausible. Ultimately, it is inconceivable that Congress by its silence changed the law to allow the private enforcement of state laws *identical* to the FDCA – when it had consistently and unequivocally prohibited the private enforcement of the federal law itself.

B. Congress' Longstanding Ban On Private Enforcement Actions Was Unaffected By FDCA Section 343-1.

The California Supreme Court largely justified its decision by pointing to FDCA section 343-1, which not only allows states to adopt laws identical to certain federal labeling requirements, but also in its view permits private parties to enforce those identical state laws. (Pet. App. 27.) Acknowledging that Congress "said absolutely nothing" about private enforcement when it enacted section 343-1 in 1990 (Pet. App. 18), the court nevertheless presumed that Congress "did not intend to alter the status quo, i.e., states may choose to permit their residents to file unfair competition or other claims based on the violation of state laws." (Pet. App. 19.) The court, however, failed to acknowledge that the "status quo" was Congress' longstanding ban on private enforcement actions in FDCA section 337.

In reaching its decision, the California Supreme Court leaned heavily on the "strong presumption against preemption" (Pet. App. 12, 35), which it claimed "applies with particular force here" (Pet. App. 13). While it is true that courts always "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *California v. ARC America Corp.*, 490 U.S. 93, 101 (1989) (internal quotations and citation omitted), the court below overlooked the fact that preemption *was* the "clear and manifest purpose of

Congress." Section 337 of the original Act is as plain as enforcement provisions come, commanding that "all" proceedings to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 349 n.4. That statutory mandate was born of Congress' decision to reject a version that would have allowed a private right of action, *National Women's Health*, 545 F. Supp. at 1179-80, and was intended to exclude private litigants from the Act's enforcement scheme, *Buckman*, 531 U.S. at 349 n.4.

Thus, when Congress in 1990 allowed states to enact laws identical to the FDCA, it was legislating in an area in which the presumption against preemption had already been overcome by its own more than fifty-year ban on private enforcement. The California Supreme Court's theory that Congress silently obliterated its more than fifty-year-old regime of exclusive government enforcement is untenable. In 1990, Congress intended to allow state *governments* – the same parties that were simultaneously permitted to bring certain enforcement actions in federal court, 21 U.S.C. § 337(b) – to enforce in state court the "little FDCA" provisions that section 343-1 allowed states to enact, but it never intended to allow private enforcement.[4]

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[4] While the court below suggested that this Court's opinions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), somehow support its decision (Pet. App. 24-26), those cases have no relevance here.

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The proper construction of this key federal statute should be settled by this Court. *See, e.g., United States v. Donovan*, 429 U.S. 413, 422 (1977) ("We granted certiorari to resolve these issues, which concern the construction of a major federal statute. . . ."); *Reliance Electric Co. v. Emerson Electric Co.*, 404 U.S. 418, 421-22 (1972) (granting certiorari petition "in order to consider an unresolved question under an important federal statute").

II. THE CALIFORNIA SUPREME COURT'S DECISION WILL HAVE PROFOUNDLY NEGATIVE CONSEQUENCES THROUGHOUT THE COUNTRY.

Exclusive government enforcement has always been an integral component of the FDCA. Congress from the start eschewed the idea of private enforcement, *National Women's Health*, 545 F. Supp. at

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Both decisions addressed only whether the challenged state law claims fell within the scope of the express preemption provisions at issue, never addressing the possibility of conflict preemption. Thus, while the lower court was correct to note that in those cases "the high court considered the impact on assertions of federal preemption of provisions similar to section 343-1" (Pet. App. 24), neither case considered other types of preemption, *see Buckman*, 531 U.S. at 352 ("*Medtronic* did not squarely address the question of implied pre-emption."); *Bates*, 544 U.S. at 458 (conc. & dis. opn. of Thomas, J.) ("Because we need only determine the ordinary meaning of [the Federal Insecticide, Fungicide, and Rodenticide Act provision at issue], the majority rightly declines to address respondent's argument that petitioners' claims are subject to other types of pre-emption.").

1179-80, instead giving the FDA a panoply of enforcement options, 21 U.S.C. §§ 332-334. Importantly, Congress also bestowed upon the FDA the authority not to prosecute "minor violations of [the FDCA] whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336. By allowing the FDA the discretion to distinguish between minor violations and ones worthy of enforcement, Congress anticipated that the government would determine whether and how to enforce the law. *See, e.g., United States v. Sullivan*, 332 U.S. 689, 694 (1948) (noting that FDCA section 336 grants the Secretary of Health and Human Services the ability to decide not to redress "technical infractions of law"); *United States v. Hunter Pharmacy, Inc.*, 213 F. Supp. 323, 324 (S.D.N.Y. 1963) ("The determination of whether a violation is of such a nature as not to require criminal prosecution to vindicate the public interest is entrusted to the judgment of the Secretary.").

Without this Court's intervention, Congress' government enforcement plan and all its inherent benefits will be lost. As the Sixth Circuit recognized in *Bailey v. Johnson*, a private cause of action under the FDCA would jeopardize the "major advantages" of government enforcement, "including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a uniform enforcement policy." 48 F.3d at 968. Under the California Supreme Court's decision, the enforcement of a vital federal statute and identical state statutes will

be left largely in the hands of class action counsel whose expertise is not in the FDCA, who have no ability to solicit comments on an enforcement policy, whose job is to represent private clients and not the public interest, and who have no ability to pursue a unitary enforcement policy.

If the California Supreme Court's decision allowing private enforcement of the FDCA stands, the reaction will be viral. The California Supreme Court is followed more frequently than any other state court, Dear & Jessen, *"Followed Rate" and Leading State Cases, 1940-2005*, 41 U.C. Davis L. Rev. 683, 693 (2007), so its decision is likely to be widely followed. Moreover, California is not the only state that would allow its unfair competition law to bring private class actions for violation of state laws identical to the FDCA. In fact, a violation of federal or state consumer protection-related statutes automatically constitutes a violation of the unfair competition laws of numerous states.[5]

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[5] *See, e.g., Cheshire Mortgage Service, Inc. v. Montes*, 612 A.2d 1130, 1143 (Conn. 1992) (holding that plaintiff's violation of the federal Truth in Lending Act and a Connecticut statute governing prepaid finance charges automatically resulted in violation of the state unfair trade practices act); *Tuckish v. Pompano Motor Co.*, 337 F. Supp. 2d 1313, 1319-20 (S.D. Fla. 2004) (holding that the violation of a Federal Trade Commission Act rule supported a cause of action under Florida's unfair trade practices act); *Ai v. Frank Huff Agency, Ltd.*, 607 P.2d 1304, 1311 (Haw. 1980), overruled on other grounds, *Robert's Hawaii School Bus, Inc. v. Laupahoehoe Transp. Co., Inc.*, 982 P.2d 853 (Haw.

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1999) (holding that a collection agency that failed to comply with state debt collection provisions also violated state's prohibition against unfair trade practices); *McCoy v. MTI Vacations, Inc.*, 650 N.E.2d 605, 607 (Ill. App. 1995) (holding that the state's consumer fraud act provides a private cause of action to persons damaged as a result of violations of Illinois' Travel Promotion Consumer Protection Act); *William Mushero, Inc. v. Hull*, 667 A.2d 853, 855 (Me. 1995) (holding that a violation of the Home Construction Contracts Act also creates liability under the state unfair trade practices act); *MacGillivary v. W. Dana Bartlett Ins. Agency of Lexington, Inc.*, 436 N.E.2d 964, 969 (Mass. App. 1982) (holding that negligent violation of a statute governing unlicensed insurers constituted violation of the state's unfair trade practices law); *Jacobs v. Rosemount Dodge-Winnebago South*, 310 N.W.2d 71, 79 (Minn. 1981) (holding that breach of an express warranty in violation of a Minnesota statute also amounts to violation of the state consumer protection act "[a]s a matter of law"); *State ex rel. Nixon v. Beer Nuts, Ltd.*, 29 S.W.3d 828, 837-38 (Mo. App. 2000) (holding that selling beer in violation of state liquor licensing requirements subjected defendant to liability under the state consumer protection statute); *Chroniak v. Golden Investment Corp.*, 983 F.2d 1140, 1147 (1st Cir. 1993) (holding that a lender's violation of New Hampshire's Second Mortgage Home Loans Act formed a predicate "unfair or deceptive practice or act" under New Hampshire's consumer protection act); *Morgan v. Air Brook Limousine, Inc.*, 510 A.2d 1197, 1205 (N.J. Super. 1986) (holding that a violation of the Federal Trade Commission rule dealing with unfair and deceptive franchising practices "constitutes a per se unconscionable commercial act or practice in violation" of the New Jersey consumer fraud act); *In re Scrimpsher*, 17 B.R. 999, 1015 (Bankr. N.D.N.Y. 1982) (holding that a violation of the federal Fair Debt Collection Practices Act subjected defendant to concurrent liability under the state consumer fraud act); *Pearce v. American Defender Life Ins. Co.*, 343 S.E.2d 174, 180 (N.C. 1986) (holding that insurer's representation in violation of state insurance law "as a matter of law constitutes an unfair or deceptive trade practice" under the state's unfair and deceptive trade practices act); *Ganson v. Vaughn*, 735 N.E.2d 483, 486 (Ohio App. 1999)

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This is not, in short, a problem that will be limited or is unique to California. In fact, federal district courts in Massachusetts and Illinois have already held that FDCA section 343-1 permits private actions under various state unfair competition laws for violation of FDCA requirements. *Vermont Pure Holdings, Ltd. v. Nestle Waters North America*, No. Civ.A. 03-11465, 2006 WL 839486, at *6 & n.5 (D. Mass. Mar. 28, 2006) (holding that plaintiff could pursue claims under the unfair competition laws of at least six different states, including Connecticut, Massachusetts, Maine, New Hampshire, New York, and Rhode Island, for violations of statutes in each of those states incorporating the FDA's definition of the term "spring water"); *Reyes v. McDonald's Corp.*, Nos. 06 C 1604, 06 C 2813, 2006 WL 3253579, at *6 (N.D. Ill. Nov. 8, 2006) (allowing a claim under the state's consumer fraud act "seeking to enforce the exact terms of the NLEA").

The certain flood of private class actions nationwide will undermine federal and state governments' ability to enforce federal labeling requirements

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(holding that failure to comply with an administrative code provision regarding refund policies and deposits in consumer transactions constitutes an automatic violation of the state consumer sales practices act); *Salois v. Mutual of Omaha Ins. Co.*, 581 P.2d 1349, 1350 (Wash. 1978) (holding that insurer's breach of duty of good faith and fair dealing by refusing to pay insured's claim for benefits was unlawful and against public policy and therefore also a violation of the state consumer protection act).

"consistently with [their] judgment and objectives." *Buckman*, 531 U.S. at 350. The federal and state governments can certainly coordinate their enforcement efforts; the FDA has even declared its intent "to work with the States to attempt to ensure that State provisions that are identical to provisions in the act are interpreted by the States in a way that is as consistent as possible with the FDA's interpretation of the Federal provisions." 58 Fed. Reg. 2457-01, 2458 (1993). The FDA, however, cannot possibly work with countless plaintiffs' lawyers across the country to ensure that their class actions are "as consistent as possible with the FDA's interpretation of the Federal provisions." Instead, inconsistent lawsuits and inconsistent judgments will abound, throwing the enforcement of the Act and identical state laws into hopeless confusion.

The adverse impact of the California Supreme Court's decision cannot be overstated. Permitting private parties to enforce the FDCA and identical state statutes will frustrate Congress' intent to keep enforcement in the hands of experienced government entities capable of coordinating their enforcement efforts. If the decision remains, class action litigation concerning alleged violations of the FDCA and identical state statutes will explode nationwide, wrecking an enforcement regime that has remained in place for the last seventy years. Because the California Supreme Court's decision will have such a radical impact on governmental discretion, oversight, and enforcement, Petitioners respectfully request that

this Court call for the views of the Solicitor General in deciding whether review is appropriate.

CONCLUSION

Congress provided for an exclusive government enforcement scheme to avoid inconsistent judgments and to preserve the governmental discretion and oversight that it believed was necessary for the Act's effective enforcement. Had Congress intended to change that deliberate, longstanding regime, it would have clearly said so. The California Supreme Court's unilateral decision to demolish Congress' well-constructed enforcement framework necessitates this Court's review.

Respectfully submitted,

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175 P.3d 1170

Supreme Court of California
FARM RAISED SALMON CASES.
No. S147171.

Feb. 11, 2008.

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MORENO, J.

Plaintiffs filed a class and representative action alleging that various grocery stores violated state law by selling artificially colored farmed salmon without

disclosing to their customers the use of color additives.[1] Defendants successfully demurred in the trial court, arguing the action was preempted by section 337(a) of title 21 of the United States Code, a provision of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 301 et seq.).[2] The Court of Appeal affirmed the resulting judgment of dismissal.

We granted review to decide whether plaintiffs' action was preempted by the FDCA. We conclude that section 337(a) does not preempt the action as plaintiffs do not seek to "enforce[ ], or to restrain violations" of, the FDCA. (§ 337(a).) Rather, plaintiffs' claims for deceptive marketing of food products are predicated on state laws establishing independent state disclosure requirements "identical to" the disclosure requirements imposed by the FDCA, something Congress explicitly approved in section 343-1. (§ 343-1(a)(3).) Accordingly, we reverse the Court of Appeal's judgment and remand the matter to that court for further proceedings consistent with our opinion.

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[1] The grocery stores include Albertson's, Inc., Safeway, Inc., The Kroger Company, Trader Joe's, Costco Wholesale Corp., Whole Foods Market, Inc., Bristol Farms, Inc., Ocean Beauty Seafoods, Inc., and various subsidiary stores owned and operated by these stores (collectively, defendants).

[2] All further unlabeled statutory references are to title 21 of the United States Code.

I. BACKGROUND

A. Facts and Procedural History

Various individuals initiated separate actions against defendants alleging the grocery stores sold artificially colored farmed salmon without disclosing to consumers the use of color additives.[3] The separate actions were coordinated in Judicial Council Coordination Proceeding No. 4329.

In March 2004, plaintiffs filed a coordinated complaint alleging as a class and representative action that fish farmers feed farm-raised salmon the chemicals astaxanthin and canthaxanthin to obtain a color of flesh resembling that of wild salmon.[4] Plaintiffs allege the flesh of farm-raised salmon appears grayish without the chemical additives and that consumers believe the color of salmon is an indication of its origin, quality, freshness, flavor, and other characteristics. Plaintiffs allege that concerns have been raised about the potential health risks of consuming

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[3] The factual and procedural history is largely taken from the Court of Appeal's opinion.

[4] While astaxanthin and canthaxanthin can occur naturally, the color additives used for feeding farmed salmon are manufactured from petrochemicals. (*See* Burros, *Issues of Purity and Pollution Leave Farmed Salmon Looking Less Rosy*, N.Y. Times (May 28, 2003) p. F1.) Salmon farmers can manipulate the flesh color of their product by increasing or decreasing the amount of chemical dye. Indeed, one of the dye manufacturers "offers salmon farmers the SalmoFan, a sort of paint wheel with assorted shades of pink, to help them create the color they think their customers want." (*Ibid.*)

the artificial coloring agents in particular and farm-raised salmon in general. They further allege that parallel federal and state laws require food labeling to state that farmed salmon is artificially colored and defendants failed to comply with those requirements. Plaintiffs also allege the failure to disclose the use of artificial coloring has caused consumers to believe farmed salmon is wild salmon.

The complaint asserts four state law causes of action: (1) violation of the unfair competition law (UCL) (Bus. & Prof.Code, § 17200 et seq.); (2) unfair or deceptive trade practices under the Consumers Legal Remedies Act (CLRA) (Civ.Code, § 1750 et seq.); (3) violation of the false advertising law (Bus. & Prof.Code, § 17500 et seq.); and (4) negligent misrepresentation. The laws alleged to be violated as a predicate for the "unlawful" prong of plaintiffs' UCL claim (*id.*, § 17200) include provisions of the state Sherman Food, Drug, and Cosmetic Law (Health & Saf.Code, § 109875 et seq.) (Sherman Law).[5]

Defendants jointly demurred on several grounds, including that (1) section 337(a)[6] preempts plaintiffs'

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[5] There is no dispute that, under California law, private parties may assert UCL claims based on violations of the Sherman Law. (*Committee on Children's Television, Inc. v. General Foods Corp.* (1983) 35 Cal.3d 197, 210-211, 197 Cal.Rptr. 783, 673 P.2d 660 (*Children's Television*).)

[6] Section 337(a) provides: "Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." Subsection (b) allows states to initiate proceedings in their

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state law claims; (2) further consideration of the complaint could conflict with regulation and enforcement by the United States Food and Drug Administration (FDA) or California's Department of Health Services (DHS), so the action should be dismissed under the primary jurisdiction doctrine; and (3) plaintiffs failed to allege affirmative representation as required in order to state a cause of action under several provisions of the CLRA. Defendants also moved to strike portions of the complaint.

The trial court sustained the demurrer as to each count, with leave to amend. The court held that section 337(a) preempts plaintiffs' state law claims, that the dispute should be referred to the FDA or the DHS under the primary jurisdiction doctrine, and that plaintiffs failed to state a claim for violation of the CLRA because they failed to allege the necessary affirmative representation. Plaintiffs elected not to amend their complaint and instead challenged on appeal the sustaining of the demurrer.

The Court of Appeal affirmed the trial court's finding of preemption, holding that section 337(a) precludes private enforcement of the FDCA, that plaintiffs' state law claims are predicated on a violation of the FDCA, and, therefore, that section 337(a)

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own name in federal court to enforce, or restrain violations of, certain provisions of the FDCA after first giving 30 days' notice to the federal government and allowing the federal government to decide whether it wants to commence an enforcement action.

impliedly preempts plaintiffs' state law claims.[7] In light of its holding, the Court of Appeal did not reach or discuss the other grounds asserted by defendants in support of their demurrer. We granted plaintiffs' petition for review.

B. Relevant Federal and State Laws

1. The FDCA Requires Disclosure of the Use of Color Additives

The FDCA prohibits the misbranding of any food. (§ 331(b).) A food "shall be deemed to be misbranded" under the FDCA if "its labeling is false or misleading in any particular. . . ." (§ 343(a).) More important to this case, a food is also deemed misbranded if "[i]t bears or contains any . . . artificial coloring . . . unless it bears labeling stating that fact. . . ." (§ 343(k).)

FDA regulations permit the use of the chemical substances astaxanthin and canthaxanthin in "the feed of salmonid fish" as color additives "to enhance the pink to orange-red color of the flesh of salmonid fish." (21 C.F.R. §§ 73.35(c) [astaxanthin], 73.75(c)(3) [canthaxanthin] (2007).) If used, however, the chemicals' presence

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[7] The state Attorney General filed an amicus curiae brief addressing defendants' section 337 argument. The brief also directed the Court of Appeal's attention to section 343-1(a)(3) and argued that the statute expressly permits states to enact laws identical to federal requirements governing the labeling of artificially colored food. While the court's opinion acknowledged and addressed the Attorney General's section 337 arguments, it did not address the section 343-1 argument.

must be declared as prescribed by the FDA (*id.*, §§ 73.35(d)(3), 73.75(d)(4)). Use of a color additive must be declared through the use of the phrases "'Artificial Color,' 'Artificial Color Added,' or 'Color Added' (or by an equally informative term that makes clear that a color additive has been used in the food)." (*Id.*, § 101.22(k)(2) (2007).) Alternatively, disclosing the actual color additive used satisfies FDA regulations. (*Ibid.*) The disclosure that a color additive has been used "shall be placed on the food or on its container or wrapper, or on any two or all three of these, as may be necessary to render such statement likely to be read by the ordinary person under customary conditions of purchase and use of such food." (*Id.*, § 101.22(c).)

2. The FDCA Permits States to Establish Identical Requirements

Congress amended the FDCA with the Nutrition Labeling and Education Act of 1990 (NLEA). (Pub.L. No. 101-535 (Nov. 8, 1990) 104 Stat. 2353.) The purpose of the NLEA was to create uniform national standards regarding the labeling of food and to prevent states from adopting inconsistent requirements with respect to the labeling of nutrients. (Remarks of Rep. Waxman, 136 Cong. Rec. 5840 (daily ed. July 30, 1990) [debate on H.R. No. 3562, 101st Cong., 2d Sess.].) To that end, the NLEA included an explicit preemption provision in the form of section 343-1(a) (Pub.L. No. 101-535, § 6 (Nov. 8, 1990) 104 Stat. 2362-2364), which provides that "no State or political

subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce – [¶] . . . [¶] (3) any requirement for the labeling of food of the type required by section . . . 343(k) of this title *that is not identical to the requirement* of such section. . . ." (§ 343-1(a), italics added.)[8]

Although section 343-1 speaks in terms of what states may *not* do, by negative implication, section 343-1 also expresses what states *may* do, i.e., states *may* establish their own requirements pertaining to the labeling of artificially colored food so long as their requirements are identical to those contained in the FDCA in section 343(k). (60 Fed.Reg. 57120 (Nov. 13, 1995) [under FDA regulations, "if the State requirement is identical to Federal law, there is no issue of preemption"]; *Consumer Justice Center v. Olympian Labs, Inc.* (2002) 99 Cal.App.4th 1056, 1065, 121 Cal.Rptr.2d 749 (*Consumer Justice*) ["[s]tates *can* enforce labeling rules which *are* identical" (original italics)]; cf. *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 495, 116 S.Ct. 2240, 135 L.Ed.2d 700 (*Medtronic*)

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[8] FDA regulations make clear that the phrase "not identical to" in section 343-1(a)(3) "does not refer to the specific words in the requirement." (21 C.F.R. § 100.1(c)(4) (2007).) "[I]f the state requirement does the same thing that the Federal law does, even if the words are not exactly the same, then it is effectively the same requirement as the Federal requirement. . . . [s]uch a State or local requirement is consistent with the Federal requirement." (60 Fed.Reg. 57120 (Nov. 13, 1995).)

[reaching same conclusion regarding similar FDCA preemption provision in section 360k].)

3. The Sherman Law Imposes Requirements "Identical to" Those Contained in Section 343(k)

Like the FDCA, the Sherman Law broadly prohibits the misbranding of food. (Health & Saf.Code, § 110765.) Among various examples of what constitutes misbranded food (*e.g.*, *id.*, § 110660 et seq.), the Sherman Law uses language "identical to" section 343(k) to provide that food is misbranded "if it bears or contains any . . . artificial coloring . . . unless its labeling states that fact." (Health & Saf.Code, § 110740.) The Sherman Law provides that disclosing the addition of "color" will suffice (*id.*, § 110725, subd. (a)) and requires that any disclosure be "prominently placed . . . and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." (*Id.*, § 110705.)

Additionally, the Sherman Law incorporates "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the [FDCA]" as "the food labeling regulations of this state." (Health & Saf.Code, § 110100, subd. (a).) Thus, California has adopted as its own the FDA regulations regarding the use of (and disclosure of the use of) astaxanthin and canthaxanthin in the feeding of farmed salmon (*see* 21 C.F.R. §§ 73.35, 73.75 (2007)).

4. Section 337 Specifies Who Has Standing to Enforce the FDCA

Originally enacted in 1938, section 337 is a standing provision, providing that "all such proceedings for the enforcement, or to restrain violations, *of* [*the FDCA*] shall be by and in the name of the United States. . . ."[9] (Act of June 25, 1938, ch. 675, § 307, 52 Stat. 1046, italics added.) Section 337 precludes private enforcement of the FDCA (§ 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341, 349, fn. 4, 352, 121 S.Ct. 1012, 148 L.Ed.2d 854 (*Buckman*)) and limits the circumstances under which states may seek to enforce the FDCA in federal court (§ 337(b)). Whether or not section 337 also precludes private claims predicated on state law is the crux of the present litigation and will be discussed at greater length below.

C. Principles of Preemption

As we have previously explained, "[t]he basic rules of preemption are not in dispute: Under the supremacy clause of the United States Constitution (art. VI, cl. 2), Congress has the power to preempt state law concerning matters that lie within the authority of Congress. [Citation.] In determining

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[9] The NLEA relabeled the original section 337 as section 337(a) (Pub.L. No. 101-535, § 4 (Nov. 8, 1990) 104 Stat. 2362) and added subsection (b). (§ 337(b); *see ante*, 72 Cal.Rptr.3d at pp. 116-117, fn. 6, 175 P.3d at p. 1174, fn. 6.)

whether federal law preempts state law, a court's task is to discern congressional intent. [Citation.] Congress's express intent in this regard will be found when Congress explicitly states that it is preempting state authority. [Citation.] Congress's implied intent to preempt is found (i) when it is clear that Congress intended, by comprehensive legislation, to occupy the entire field of regulation, leaving no room for the states to supplement federal law [citation]; (ii) when compliance with both federal and state regulations is an impossibility [citation]; or (iii) when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' [Citations.]" (*Bronco Wine Co. v. Jolly* (2004) 33 Cal.4th 943, 955, 17 Cal.Rptr.3d 180, 95 P.3d 422 (*Bronco Wine*); *Viva! International Voice for Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal.4th 929, 935-936, 63 Cal.Rptr.3d 50, 162 P.3d 569 (*Viva! International*).) It is well established that the party who asserts that a state law is preempted bears the burden of so demonstrating. (*Viva! International, supra,* 41 Cal.4th at p. 936, 63 Cal.Rptr.3d 50, 162 P.3d 569; *Bronco Wine, supra,* 33 Cal.4th at p. 956, 17 Cal.Rptr.3d 180, 95 P.3d 422.)

The interpretation of the federal law at issue here is further informed by a strong presumption against preemption. (*See Medtronic, supra,* 518 U.S. at p. 485, 116 S.Ct. 2240; *see also Viva! International, supra,* 41 Cal.4th at p. 938, 63 Cal.Rptr.3d 50, 162 P.3d 569; *Bronco Wine, supra,* 33 Cal.4th at p. 974, 17 Cal.Rptr.3d 180, 95 P.3d 422.) "[B]ecause the States

are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action. In all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' [citation] we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' [Citations.]" (*Medtronic, supra,* 518 U.S. at p. 485, 116 S.Ct. 2240; *Bates v. Dow Agrosciences LLC* (2005) 544 U.S. 431, 449, 125 S.Ct. 1788, 161 L.Ed.2d 687 (*Bates*); *Big Creek Lumber Co. v. County of Santa Cruz* (2006) 38 Cal.4th 1139, 1150, fn. 7, 45 Cal.Rptr.3d 21, 136 P.3d 821.) We apply this presumption to the *existence* as well as the *scope* of preemption. (*Medtronic, supra,* 518 U.S. at p. 485, 116 S.Ct. 2240.)

There can be no doubt that the presumption applies with particular force here. (*See Bronco Wine, supra,* 33 Cal.4th at p. 974, 17 Cal.Rptr.3d 180, 95 P.3d 422.) As the Court of Appeal acknowledged here, "[c]onsumer protection laws such as the [UCL], false advertising law, and CLRA, are within the states' historic police powers and therefore are subject to the presumption against preemption." Laws regulating the proper marketing of food, including the prevention of deceptive sales practices, are likewise within states' historic police powers. (*Florida Lime & Avocado Growers v. Paul* (1963) 373 U.S. 132, 144, 83 S.Ct. 1210, 10 L.Ed.2d 248; *Bronco Wine, supra,* 33

Cal.4th at pp. 959-961, 17 Cal.Rptr.3d 180, 95 P.3d 422 [describing history of state regulation].) Indeed, as early as the 1860's, California was enacting laws regulating food marketing. (*See, e.g.*, Stats. 1862, ch. 365, pp. 484-485 [prohibiting sale of adulterated and misbranded food]; *Bronco Wine, supra,* 33 Cal.4th at pp. 961-963, 17 Cal.Rptr.3d 180, 95 P.3d 422.)

It is with these principles in mind that we consider whether it was the "'clear and manifest purpose'" of Congress (*Medtronic, supra,* 518 U.S. at p. 485, 116 S.Ct. 2240) to preclude states from providing private remedies for the violations of the state statutes at issue here.

II. DISCUSSION

We begin by noting the type of preemption defendants assert here.[10] As the Court of Appeal concluded, it is clear that Congress has not expressly preempted private claims predicated on *state laws* imposing requirements identical to those contained in the FDCA (*see* §§ 337, 343-1), and defendants do not claim otherwise. Neither do defendants contend that plaintiffs' action is impliedly preempted as a result of Congress occupying the field. Nor do defendants

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[10] We apply a de novo standard of review because this case was resolved on demurrer (*McCall v. PacifiCare of Cal., Inc.* (2001) 25 Cal.4th 412, 415, 106 Cal.Rptr.2d 271, 21 P.3d 1189) and because federal preemption presents a pure question of law (*Spielholz v. Superior Court* (2001) 86 Cal.App.4th 1366, 1371, 104 Cal.Rptr.2d 197).

argue the action is preempted because compliance with both state and federal laws is impossible – as state and federal laws impose identical requirements regarding the disclosure of the use of artificial coloring, compliance with one necessarily ensures compliance with the other. (*Compare*, *e.g.*, § 343(k) with Health & Saf.Code, § 110740.) Instead, defendants assert plaintiffs' claims are impliedly preempted because they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

The Court of Appeal concluded that plaintiffs' action was indeed impliedly preempted, basing its holding solely on its reading and application of section 337(a). While the Court of Appeal acknowledged that the statute's plain language limits its scope to efforts that seek to enforce the FDCA itself, it nonetheless concluded that section 337(a) also operates to preempt plaintiffs' purely state law claims. The Court of Appeal reasoned that, because section 337(a) explicitly bars the private enforcement of FDCA provisions (*Buckman, supra,* 531 U.S. at pp. 349, fn. 4, 352, 121 S.Ct. 1012), section 337(a) must therefore also impliedly bar private claims predicated on state provisions imposing requirements identical to those contained in the FDCA. However plausible the Court of Appeal's reasoning may appear when section 337(a) is considered in isolation, its reasoning is seriously undermined when section 343-1 is taken

into account.[11] Accordingly, we begin with a discussion of that statute.

As previously mentioned (*ante,* 72 Cal.Rptr.3d at p. 117, fn. 7, 175 P.3d at p. 1174, fn. 7), the Attorney General filed an amicus curiae brief in the lower court in which it discussed the impact of section 343-1 at length. Defendants filed an answer fully responding to the argument. After the Court of Appeal issued its opinion without discussing the statute, the Attorney General filed a letter in support of plaintiffs' petition for review in which it again addressed the provision. Defendants addressed the argument in their response letter. In neither their answer to the amicus curiae brief nor their response to the Attorney General's letter did defendants assert that section 343-1 had not been properly raised. Plaintiffs then discussed section 343-1 in their opening brief in this court and defendants fully briefed the issue while simultaneously arguing plaintiffs should not be allowed to raise it. Accordingly, all the parties have had a reasonable opportunity to brief this issue and we may properly consider it. (Cal. Rules of Court, rule 8.516(b)(2).)

Additionally, while plaintiffs' petition for review did not explicitly cite section 343-1, it did broadly

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[11] Defendants ask this court to ignore section 343-1 when considering Congress's intent, contending plaintiffs have not properly raised the statute and implying the Court of Appeal was not given an opportunity to consider the issue. We disagree and decline defendants' invitation to disregard section 343-1.

raise the issue of "whether the FDCA preempts parallel state law requirements." Because our central task in preemption analysis is to discern Congress's intent (*Bronco Wine, supra,* 33 Cal.4th at p. 955, 17 Cal.Rptr.3d 180, 95 P.3d 422), it is appropriate to discuss a pertinent FDCA provision shedding light on that intent.

Moreover, the impact of section 343-1 presents a purely legal issue and does not require the further development of a factual record. We have previously allowed parties to "'advance new theories on appeal when the issue posed is purely a question of law based on undisputed facts, and involves important questions of public policy.'" (*Cedars-Sinai Medical Center v. Superior Court* (1998) 18 Cal.4th 1, 6, 74 Cal.Rptr.2d 248, 954 P.2d 511.)

A. Section 343-1 Permits States to Adopt Identical Requirements

The words of section 343-1 clearly and unmistakably evince Congress's intent to authorize states to establish laws that are "identical to" federal law. (§ 343-1; *Consumer Justice, supra,* 99 Cal.App.4th at p. 1065, 121 Cal.Rptr.2d 749.) That is precisely what California did in enacting the Sherman Law. The Sherman Law provision prohibiting misbranding with regard to the use of color additives (Health & Saf.Code, § 110740) is identical to section 343(k), the parallel federal requirement specifically listed in section 343-1 as one of the federal statutes covered by

the express preemption provision. Additionally, the Sherman Law incorporates all of the food labeling regulations promulgated by the FDA (Health & Saf.Code, § 110100, subd. (a)), including those having to do with the use of astaxanthin and canthaxanthin in the feeding of farmed salmon (21 C.F.R. §§ 73.35, 73.75 (2007)). Accordingly, the state requirements at issue here are explicitly permitted by section 343-1. (*See Consumer Justice, supra,* 99 Cal.App.4th at p. 1065, 121 Cal.Rptr.2d 749 ["[s]tates *can* enforce labeling rules which *are* identical" (original italics)].)

While Congress clearly stated its intent to allow states to establish their own identical laws, it said absolutely nothing about proscribing the range of available remedies states might choose to provide for the violation of those laws, such as private actions. Nor is there anything in the legislative history suggesting that any proponent of the legislation intended a sweeping preemption of private actions predicated on requirements contained in state laws. Defendants cite portions of the legislative history for that proposition, but the cited excerpts actually bolster our conclusion. For example, defendants point to the remarks of Representative Henry Waxman, who originally introduced the NLEA in the House of Representatives: "[The NLEA] recognizes the importance of the State role: by allowing *States* to adopt standards that are identical to the Federal standard, which may be enforced in State court; by allowing the *States* to enforce the Federal standard in Federal

court." (Remarks of Rep. Waxman, 136 Cong. Rec. 1539 (daily ed. July 30, 1990), italics added.)

Far from establishing that Congress intended to preclude private claims based on state laws, Representative Waxman's remarks suggest the opposite. By explicitly stating that the NLEA would allow states to enforce the federal requirements in federal court, but not discussing who would be allowed to enforce the identical state requirements, the remarks suggest that Congress did not intend to alter the status quo, i.e., states may choose to permit their residents to file unfair competition or other claims based on the violation of state laws (*see, e.g., Children's Television, supra,* 35 Cal.3d at pp. 210-211, 197 Cal.Rptr. 783, 673 P.2d 660).[12] If Congress intended to permit states to enact identical laws on the one hand, but preclude states from providing private remedies for violations of those laws on the other hand, "its failure even to hint at it is spectacularly odd." (*Medtronic, supra,* 518 U.S. at p. 491, 116 S.Ct. 2240 (plur. opn. of Stevens, J.).) Congressional silence on this point is all the

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[12] Indeed, the NLEA was enacted in 1990 primarily to establish a national uniform labeling standard in place of the patchwork of different state standards that existed at the time. Under defendants' interpretation of the FDCA, private claims based on those pre-NLEA state labeling laws would have been permitted (since they were presumably different from the FDCA), but Congress's adoption of a uniform standard in the form of the NLEA had the effect of eliminating private causes of action based on state labeling laws. It is hard to believe that Congress would have intended such a result without saying so.

more strange in light of Congress's presumed awareness that "virtually every state in the nation permits one or more nongovernmental parties to enforce state . . . laws of general applicability prohibiting deceptive or unfair acts and practices in the marketplace." (Annot., Right to Private Action Under State Consumer Protection Act – Preconditions to Action (2004) 117 A.L.R.5th 155.)[13]

Further undermining defendants' interpretation is the fact that Congress made clear that the preemptive scope of section 343-1 was to sweep no further than the plain language of the statute itself. In NLEA section 6(c)(1) (an uncodified provision), Congress provided that "[t]he [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [section 343-1] of the [FDCA]." (Pub.L. No. 101-535, § 6(c)(1) (Nov. 8, 1990), 104 Stat. 2364.) Thus, Congress's decision not to expressly supplant private claims based on those state laws authorized by section 343-1 should be interpreted as its considered decision to continue to allow states to provide such private remedies.

The language of this uncodified provision is significant for two additional reasons. First, it evidences an intent to allow state and federal regulation

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[13] For example, we held in *Children's Television, supra,* 35 Cal.3d at pages 210, 197 Cal.Rptr. 783, 673 P.2d 660 to 211, that, in California, "any unlawful business practice, *including violations of the Sherman law,* may be redressed by a [UCL] private action." (Italics added.)

to co-exist. "Where Congress establishes a regime of dual state-federal regulation, 'conflict-preemption analysis must be applied sensitively . . . so as to prevent the diminution of the role Congress reserved to the States while at the same time preserving the federal role.' [Citations.]"[14] (*Viva! International, supra,* 41 Cal.4th at p. 942, 63 Cal.Rptr.3d 50, 162 P.3d 569.) Defendants' interpretation would substantially interfere with state legal remedies, "producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of remedy for the [plaintiffs'] alleged injuries." (*Medtronic, supra,* 518 U.S. at pp. 488-489, 116 S.Ct. 2240 (plur. opn. of Stevens, J.).)

Second, the provision's language is significant because it informs our analysis of the existence of any implied preemption. "[A]n express definition of the pre-emptive reach of a statute 'implies' – *i.e.,* supports a reasonable inference – that Congress did not intend to pre-empt other matters. . . ." (*Freightliner Corp. v. Myrick* (1995) 514 U.S. 280, 288, 115 S.Ct. 1483, 131 L.Ed.2d 385.) While an express clause does not foreclose an inquiry into implied conflict preemption in all cases (*Geier v. American Honda Motor Co., Inc.*

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[14] Indeed, during debate on the NLEA, Congress recognized the important role states' laws have in consumer protection. "The States have played an invaluable role by enforcing State food labeling and advertising laws at a time when consumers have been bombarded with health claims." (H.R.Rep. No. 101-980, 2d Sess., p. 19 (Nov. 14, 1990); *see* remarks of Rep. Waxman, 136 Cong. Rec. 5840 (daily ed. July 30, 1990).)

(2000) 529 U.S. 861, 869, 120 S.Ct. 1913, 146 L.Ed.2d 914), deference should be paid to Congress's detailed attempt to clearly define the scope of preemption under the FDCA. (*See Viva! International, supra,* 41 Cal.4th at p. 945, 63 Cal.Rptr.3d 50, 162 P.3d 569 ["Congress has expressly identified the scope of the state law it intends to preempt; hence, we infer Congress intended to preempt no more than that absent sound contrary evidence."].)

Various provisions of the FDCA clearly demonstrate that "Congress knows how to write a preemption clause" when it wants to (*Consumer Justice, supra,* 99 Cal.App.4th at p. 1059, 121 Cal.Rptr.2d 749) and that "the [FDCA] evidences, far from implied preemption, an instance of implied *non* preemption." (*Id.* at p. 1063, 121 Cal.Rptr.2d 749.) Congress enacted numerous specific express preemption provisions in the FDCA. (*See, e.g.*, §§ 360k (medical devices), 360ss (radiation emissions), 379r (nonprescription drugs), 379s (cosmetics).) The inference to be drawn from these provisions is that Congress, in light of the history of dual state-federal cooperation in this area, did not intend to limit states' options in a broad fashion. Indeed, the preemption provision at issue here, section 343-1, demonstrates Congress's care in deciding what to preempt and what to allow. Section 343-1 is notable both for the number of misbranding provisions it deals with (approximately 20) and for

the detailed nature of its preemptive scope.[15] The language of section 343-1 and the NLEA's express preemption provision is further evidence that Congress chose carefully the manner with which it preempted certain state labeling laws. Defendants have not provided sufficient evidence to contradict the inference that Congress intended a narrow interpretation of the scope of preemption.

In support of their argument that, notwithstanding section 343-1, plaintiffs' action is preempted by section 337, defendants point to NLEA section 6(c)(3) (an uncodified provision) (Pub.L. No. 101-535, § 6(c)(3) (Nov. 8, 1990), 104 Stat. 2364). That provision states that section 343-1 "shall not be construed to affect preemption, express or implied, of *any such requirement* of a State or political subdivision, which may arise under the Constitution, any provision of the [FDCA] not amended by section [343-1], or . . . any Federal regulation, order, or other final agency action. . . ." (Pub.L. No. 101-535, § 6(c)(3) (Nov. 8, 1990), 104 Stat. 2364, italics added.)

This provision is inapplicable to this case for two reasons. First, the phrase "any such requirement" in NLEA section 6(c)(3) refers to the "requirement" discussed in NLEA section 6(c)(2) (Pub.L. No. 101-535,

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[15] The statute, for example, does not apply to requirements governing maple syrup. (Gold, *Legal Strategies to Address the Misrepresentation of Vermont Maple Syrup* (2004) 59 Food & Drug L.J. 93, 103 & fn. 78.)

§ 6(c)(2) (Nov. 8, 1990), 104 Stat. 2364). In NLEA section 6(c)(2), Congress provided that section 343-1 does not apply "to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food. . . ." (Pub.L. No. 101-535, § 6(c)(2) (Nov. 8, 1990), 104 Stat. 2364.) Thus, read in context, it is clear that the phrase "any such requirement" in NLEA section 6(c)(3) refers to the food safety labeling requirement discussed in the immediately preceding provision, NLEA section 6(c)(2). Second, it is undisputed that section 337 bars private enforcement of the FDCA – no one contends section 343-1 alters that conclusion. However, plaintiffs do not seek to enforce the FDCA. Their action is based on the violation of *state law* – albeit state law that is, in compliance with section 343-1, identical to FDCA provisions. Concluding that section 343-1 permits private claims based on state law does not affect section 337' s preemption of efforts to enforce the FDCA.

In *Medtronic, supra,* 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700, and *Bates, supra,* 544 U.S. 431, 125 S.Ct. 1788, 161 L.Ed.2d 687, the high court considered the impact on assertions of federal preemption of provisions similar to section 343-1. In both cases the defendants claimed private suits to enforce state laws identical to federal laws were preempted by federal law. And, in both cases, the high court disagreed.

In *Medtronic, supra,* 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700, the plaintiffs filed a private

state law negligence action against the manufacturer of an allegedly defective pacemaker. The defendants argued that the plaintiffs' action was preempted by the FDCA, as amended by the Medical Device Amendments of 1976 (MDA) (Pub.L. No. 94-295 (May 28, 1976) 90 Stat. 539). (*Medtronic, supra,* 518 U.S. at p. 474, 116 S.Ct. 2240.) The high court, relying on a preemption provision contained in the MDA (§ 360k), disagreed and held that the action was not pre-empted.

Like section 343-1, section 360k provides, "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – [¶] (1) which is different from, or in addition to, any requirement applicable under this chapter to the device. . . ." (§ 360k(a); *see Medtronic, supra,* 518 U.S. at pp. 481-482, 116 S.Ct. 2240.) Interpreting this provision, the high court concluded that Congress did not intend to preempt "state rules that merely duplicate some or all of [the] federal requirements." (*Medtronic, supra,* at p. 492, 116 S.Ct. 2240.) The high court further reasoned that because Congress authorized states to adopt identical requirements, states were also free to provide for private remedies for violations of those requirements. "[I]t is clear that the [plaintiffs'] allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations. At least these claims, [the plaintiffs] suggest, can be maintained without being pre-empted by § 360k, and we agree. [¶] Nothing in § 360k denies [a state] the

right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." (*Medtronic, supra,* 518 U.S. at p. 495, 116 S.Ct. 2240).

In *Bates, supra,* 544 U.S. 431, 125 S.Ct. 1788, 161 L.Ed.2d 687, the high court considered whether plaintiffs' private state law action was preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. § 136 et seq.). The plaintiffs there were Texas peanut farmers who alleged that their crops had been severely damaged by the application of the defendant's pesticide, which had been conditionally registered by the Environmental Protection Agency. (*Bates, supra,* 544 U.S. at p. 435, 125 S.Ct. 1788.) The defendant argued FIFRA preempted the plaintiffs' action. (*Ibid.*)

Like the provision at issue in *Medtronic,* FIFRA contains a preemption provision similar to section 343-1, which provides that states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter" (7 U.S.C. § 136v(b); *see Bates, supra,* 544 U.S. at p. 436, 125 S.Ct. 1788). The *Bates* court held that "[t]he imposition of state sanctions for violating state rules that merely duplicate federal requirements is equally consistent with the text of [7 U.S.C.] § 136v." (*Bates, supra,* 544 U.S. at p. 442, 125 S.Ct. 1788.) Additionally, although FIFRA did not provide a federal remedy to the farmers, the high court concluded that "nothing in [7 U.S.C.] § 136v(b) precludes States from providing

such a remedy." (*Bates, supra,* 544 U.S. at p. 448, 125 S.Ct. 1788.)

Accordingly, in light of the plain statutory language of section 343-1, and the high court's construction of similar preemption language, we conclude that Congress intended to allow states to establish their own requirements so long as they are identical to those contained in section 343(k), which California has done in the form of the Sherman Law. We further conclude that nothing in the text of section 343-1 or its legislative history supports the assertion that Congress intended to limit the scope of remedies states might choose to provide for the violations of those state laws. We therefore turn to a consideration of whether, notwithstanding section 343-1, section 337 provides a basis for the implied preemption of plaintiffs' claims.

B. Section 337 Does Not Impliedly Preempt Plaintiffs' State Claims

To briefly recap, section 337 is the FDCA standing provision. Section 337(a) provides that, except as set forth in section 337(b), "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." Section 337(b) allows states to initiate proceedings in their own name in federal court to enforce, or restrain violations of, certain provisions of the FDCA. However, before so doing, a state must give 30 days' notice to the federal government. (§ 337(b).) The federal

government may then decide whether it wants to commence an enforcement action in court and, if it does, the state is precluded from acting to enforce the FDCA. (*Ibid.*)

The crux of defendants' preemption argument is that plaintiffs' private state claims are precluded because they improperly seek to enforce the FDCA in violation of section 337(a). Defendants' starting assumption is incorrect. Plaintiffs do not seek to enforce the FDCA; rather, their deceptive marketing claims are predicated on violations of obligations imposed by the Sherman Law, something that state law undisputedly allows (*Children's Television, supra,* 35 Cal.3d at pp. 210-211, 197 Cal.Rptr. 783, 673 P.2d 660; *cf. Stop Youth Addiction, Inc. v. Lucky Stores, Inc.* (1998) 17 Cal.4th 553, 562-563, 71 Cal.Rptr.2d 731, 950 P.2d 1086). That the Sherman Law imposes obligations identical to those imposed by the FDCA, as it must under section 343-1, does not substantively transform plaintiffs' action into one seeking to enforce federal law. Rather, it merely reflects Congress's considered judgment that states should uniformly regulate food labeling using identical standards. Indeed, while the high court in *Medtronic* did not expressly consider the impact of section 337 on the private state action at issue there, it held that those plaintiffs' private actions were permitted *because* they were identical to the FDCA. (*Medtronic, supra,* 518 U.S. at p. 495, 116 S.Ct. 2240.) It is difficult to believe the high court would have so held if section 337 expressed a "clear and manifest" intent (*Medtronic,* at

p. 485, 116 S.Ct. 2240) to preclude private actions based on state laws explicitly authorized by the FDCA in section 343-1.

Section 337 does not apply to the state law claims presented here. The statute, by its very terms, only implicates efforts to enforce *federal* law. What section 337 does *not* do is limit, prohibit, or affect private claims predicated on *state* laws. (*See Consumer Justice, supra,* 99 Cal.App.4th at p. 1067, fn. 17, 121 Cal.Rptr.2d 749 ["The underlying assumption [in the defendants' briefing] is that this lawsuit is somehow an attempt to use state unfair competition laws to enforce *federal* laws. No, the lawsuit is about state unfair advertising laws."].)[16] The FDA has opined that because "[section 337] applies only to proceedings to enforce the [FDCA]" (58 Fed.Reg. 2458 (Jan. 6, 1993)), "[n]othing in [section 337] would preclude a State from taking action against a particular food under *its own State law*. . . ."[17] (58 Fed.Reg. 2458,

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[16] Defendants claim *Consumer Justice* is distinguishable. They reason that section 337 was not implicated in that case because the plaintiffs' false advertising claims there did not raise an issue "committed to the FDA," and could not "be properly characterized as an attempt to circumvent the [FDCA's] express prohibition on private causes of action . . . " (*Consumer Justice, supra,* 99 Cal.App.4th at p. 1064, 121 Cal.Rptr.2d 749). However, the same is true of plaintiffs' state law claims here. Rather than raising issues "committed to the FDA," plaintiffs' claims arise under laws that section 343-1 explicitly authorizes states to enact.

[17] We note that, as the FDA is the federal agency that Congress has authorized to implement and enforce the FDCA

(Continued on following page)

italics added.) Nor does section 337 affect the ability of states to provide a private remedy for violations of their laws if they so choose.[18] One treatise has noted that "[p]laintiffs may sue under state unfair trade practice laws for omissions that would fit under either FDA or state trade laws. [Fn. omitted.]" (2 O'Reilly, Food and Drug Administration (3d ed.2007) § 26:32, p. 26-43; *see Children's Television, supra,* 35 Cal.3d at pp. 210-211, 197 Cal.Rptr. 783, 673 P.2d 660.)

No court, particularly after passage of the NLEA, has ever held that states may not provide a private remedy for the violation of state laws imposing requirements identical to those imposed by federal law. The cases defendants cite are inapposite, all dealing with efforts to use state laws to directly enforce the FDCA itself. For example, defendants cite *Summit Tech., Inc. v. High-Line Medical Instruments, Co.* (C.D.Cal.1996) 933 F.Supp. 918. However, in that case, the district court allowed the plaintiffs UCL

(§ 371), the FDA is "uniquely qualified to determine whether a particular form of state law . . . should be pre-empted." (*Medtronic, supra,* 518 U.S. at p. 496, 116 S.Ct. 2240; *see Thompson v. Western States Medical Center* (2002) 535 U.S. 357, 362, 122 S.Ct. 1497, 152 L.Ed.2d 563.)

[18] In their briefs, the parties discuss an unpublished federal district court opinion which came to the same conclusion when considering nearly identical facts. (*Vermont Pure Holdings, Ltd. v. Nestle Waters North America, Inc.* (D.Mass., Mar. 28, 2006, No. Civ.A.03-11465) 2006 WL 839486, *6, fn. 3.) Citing unpublished *federal* opinions does not violate our rules. (Cal. Rules of Court, rule 8.1115.) We find the court's reasoning persuasive.

claim to proceed, acknowledging that "under [the UCL], Plaintiff may redress violations of the California Sherman Act. . . ." (*Summit Tech., supra,* 933 F.Supp. at p. 943.) Defendants rely heavily on a footnote in the decision stating, "This is true unless federal law preempts such an action. Thus, a Plaintiff may not bring a [UCL] claim that is, in fact, an attempt to state a claim under the FDCA." (*Summit Tech., supra,* 933 F.Supp. at p. 943, fn. 21.) However, as previously explained, plaintiffs' claims arise out of violations of the Sherman Law, not out of the FDCA itself.

The other cases cited by defendants are similarly unavailing. They invariably deal with a party seeking to enforce (sometimes through the use of state law) the FDCA. The cases are also notable for what they do not address – none involve state laws explicitly authorized by section 343-1 or a similar statute. For example, in *Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc.* (D.Md.2006) 419 F.Supp.2d 715, a pharmaceutical company sued its competitor over the marketing and sale of drugs. The defendant company asserted a state-law unclean hands defense, arguing that the plaintiffs' drugs were being marketed in violation of the FDCA. The district court rejected the defense, reasoning that, "[b]ecause [the defense] requires direct application of the FDCA, which only the FDA is entitled to enforce, these arguments are precluded." (*Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc., supra,* 419 F.Supp.2d at p. 727.)

Defendants cite *Fraker v. KFC Corp.* (S.D.Cal., Apr. 30, 2007, No. 06-CV-01284) 2007 WL 1296571 in their supplemental brief, arguing it is a recent example of a court reaching this issue. However, as with the previous cases, *Fraker* is inapplicable. The plaintiff in *Fraker* brought state law claims against KFC Corporation (formerly Kentucky Fried Chicken) alleging that the defendant misrepresented its product as healthy when it was in fact high in "trans" fat content. (*Id.*, at p. *1.) In dismissing the plaintiff's claims as preempted, the district court noted that the complaint alleged defendant violated the FDCA, misbranded its food in violation of federal regulations, and made actionable health claims in violation of federal regulations. (*Fraker v. KFC Corp., supra,* 2007 WL 1296571 at p. *3.) Accordingly, the court concluded that the state law claims were impermissibly founded on violations of the FDCA and were thus preempted by section 337. (*Fraker v. KFC Corp., supra,* 2007 WL 1296571 at pp. *3-4.)

All of these cases rejected claims or defenses because they were based on violations of the FDCA itself.[19] The district courts reasoned that directly applying the FDCA, as would have been required,

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[19] At oral argument, defendants' counsel cited *Bailey v. Johnson* (6th Cir.1995) 48 F.3d 965. However, for the same reasons as discussed above, *Bailey* is unlike the case presented here. The plaintiffs in *Bailey* argued that "the FDCA created a private, federal right of action." (*Bailey v. Johnson, supra,* 48 F.3d at p. 966.) Plaintiffs here make no such claim.

would run afoul of section 337. By contrast, plaintiffs' claims in this case do not require referring to, or applying, the FDCA. Plaintiffs' claims are based on violation of the Sherman Law and can be resolved with reference to state law alone. Additionally, none of these cited cases considered the impact of section 343-1. Given that section 343-1 explicitly authorizes the enactment of identical state labeling laws, that provision is an important distinction between the cases defendants cite and the one presented here. In short, defendants have not identified any case law to support their argument that Congress clearly and manifestly intended to impliedly preempt with section 337 what it explicitly authorized with section 343-1.

We note also that, as in *Medtronic,* the implication of defendants "sweeping interpretation" would interfere greatly with state legal remedies, "producing a serious intrusion into state sovereignty. . . ." (*Medtronic, supra,* 518 U.S. at p. 488, 116 S.Ct. 2240 (plur. opn. of Stevens, J.).) Defendants argue that the identical requirements contained in the Sherman Law may only be enforced by the state itself, and may not be the basis of private claims. However, if section 337(a)'s explicit preclusion of private enforcement of the FDCA impliedly preempts private claims based on identical state laws, as defendants argue, then it necessarily follows that section 337(b)'s explicit conditions on state enforcement of the FDCA in federal court must also impliedly limit states' enforcement of their own laws in state court. It cannot

be the case that states must give the federal government 30 days notice before seeking to enforce their own laws in state court (as section 337(b) requires when states seek to enforce the FDCA in federal court) and defendants do not argue otherwise.

Defendants assert that allowing private claims based on identical laws in state court would render section 337 meaningless because states would be required to give the FDA notice before initiating actions but private parties would not. This argument misunderstands the scope of section 337 and conflates efforts to enforce federal law with efforts based on state law. As previously discussed, section 337 is only concerned with enforcement of *federal law, i.e.*, the FDCA. If a state brings an action to enforce the FDCA in federal court, it must first notify the FDA under section 337(b). On the other hand, defendants concede that states may enforce their own laws in state court without notifying the FDA at all, even though the laws impose requirements identical to those contained in the FDCA. Defendants identify no persuasive rationale to explain why private claims based on these same state laws would be of any greater concern to Congress than California's enforcement of state laws – in both instances, state laws identical to the FDCA are enforced without first notifying the FDA.

In conclusion, while allowing private remedies based on violations of state laws identical to the FDCA may arguably result in actions that the FDA itself might not have pursued, Congress appears to have made a conscious choice not to preclude such

actions. Defendants assertion that Congress intended, without so saying, to limit states longstanding ability to allow private remedies for violations of their own laws has no support in either statutory language, legislative history, or case law – and therefore defendants have not overcome the strong presumption against preemption applicable here, as is their burden (*Medtronic, supra,* 518 U.S at p. 485, 116 S.Ct. 2240; *Viva! International, supra,* 41 Cal.4th at p. 936, 63 Cal.Rptr.3d 50, 162 P.3d 569). We accordingly hold that section 337 does not impliedly preempt private actions based on violations of state laws explicitly authorized by section 343-1.

III. DISPOSITION

The judgment of the Court of Appeal is reversed and the matter is remanded to that court for further proceedings consistent with this opinion.

WE CONCUR: KENNARD, Acting C.J., BAXTER, WERDEGAR, CHIN, CORRIGAN and MIHARA, JJ.*

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* Associate Justice, Court of Appeal, Sixth Appellate District, assigned by the Acting Chief Justice pursuant to *article VI, section 6 of the California Constitution.*

142 Cal.App.4th 805

Court of Appeal, Second District,
Division 3, California.

FARM RAISED SALMON CASES.

No. B182901.

Aug. 31, 2006.
Review Granted Dec. 13, 2006.

Hagens Berman Sobol Shapiro, Los Angeles, Craig R. Spiegel, Lee M. Gordon, Elaine T. Byszewski, Los [sic] and Steve W. Berman, for Plaintiffs and Appellants.

Bill Lockyer, Attorney General, Albert Norman Shelden, Assistant Attorney General, and Ronald A. Reiter, Deputy Attorney General as Amicus Curiae on behalf of Plaintiffs and Appellants.

Akin Gump Strauss Hauer & Feld, Rex S. Heinke, David C. Allen, Johanna R. Shargel, Los Angeles; Streeter & Nangano, Thomas Barclay, Michael Nangano, Michael L. Coates, Los Angeles; Greenberg, Glusker, Fields, Claman, Machtinger & Kinsella, Norman Howard Levine, Los Angeles; Ervin, Cohen & Jessup, Allan B. Cooper, Beverly Hills, Tamara L. Dewar, Encino; O'Melveny & Myers, Carla J. Christofferson, Los Angeles; Seyfarth Shaw, Jay W. Connolly, San Francisco, and Geoff S. Long, for Defendants and Respondents.

CROSKEY, J.

Several individuals commenced separate actions against owners and operators of grocery stores alleging that the defendants sold artificially colored farmed salmon without disclosing to consumers the artificial coloring. The actions were coordinated in Farm Raised Salmon Cases, Judicial Council Coordination Proceeding No. 4329. The plaintiffs filed a coordinated complaint alleging as a class and representative action counts for unfair competition, violation of the Consumers Legal Remedies Act (CLRA) (Civ.Code, § 1750 et seq.), false advertising, and negligent misrepresentation. The superior court sustained a demurrer to the complaint on the grounds that the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 301 et seq.) preempted each cause of action, that the dispute should be referred to the United States Food and Drug Administration (FDA) or the California Department of Health Services (DHS) under the primary jurisdiction doctrine, and that the plaintiffs failed to state a cause of action for violation of the CLRA. In finding preemption the court relied primarily on section 337(a) of title 21 United States Code (section 337(a)), which states that an action to enforce the FDCA must be by and in the name of the United States. The plaintiffs appeal the judgment.

We conclude that in section 337(a) Congress made clear its intention to preclude private enforcement of the FDCA, that a state law private right of action based on an FDCA violation would frustrate the purposes of exclusive federal and state governmental

prosecution of the act, and that section 337(a) impliedly preempts all of the plaintiffs' causes of action. We therefore affirm the judgment without reaching or discussing the other grounds asserted by the defendants in support of their demurrer.

FACTUAL AND PROCEDURAL BACKGROUND

The plaintiffs in their consolidated and amended complaint filed in March 2004 allege that fish farmers feed farmed salmon the chemicals canthaxanthin and astaxanthin to obtain a color of flesh resembling that of wild salmon. They allege that the flesh of farmed salmon would appear grayish without the chemical additives and that consumers believe that the color of salmon is an indication of its origin, quality, freshness, flavor, and other characteristics. They allege that concerns have been raised about the potential health risks of consuming the artificial coloring agents in particular and farm-raised salmon in general. The plaintiffs allege that the FDCA and parallel state laws require food labeling to state that farmed salmon is artificially colored and that the defendants have failed to comply with those requirements. They allege that the failure to disclose the artificial color has caused consumers to believe that farmed salmon is wild salmon.

The complaint alleges counts for (1) unfair and unlawful business acts and practices in violation of the unfair competition law (Bus. & Prof.Code, § 17200 et seq.); (2) unfair or deceptive trade practices under

the CLRA; (3) false and misleading advertising in violation of the false advertising law (Bus. & Prof.Code, § 17500 et seq.); and (4) negligent misrepresentation. The laws alleged to be violated as a predicate for the unfair competition law count include provisions of the FDCA and California's Sherman Food, Drug, and Cosmetic Law (Sherman Law) (Health & Saf.Code, § 109875 et seq.), a provision of the CLRA, and Penal Code section 383. The complaint alleges a representative and class action on behalf of the plaintiffs and others similarly situated.

The defendants jointly demurred to the complaint on several grounds, including that (1) section 337(a) expressly precludes a private right of action to enforce the FDCA and therefore impliedly preempts an action under state law by a private party based on an FDCA violation, and each count of the plaintiffs' complaint is based on alleged violations of the FDCA, so section 337(a) preempts all of the counts alleged in the complaint;[1] (2) FURTHER CONSIDERATION of the plaintiffs' complaint by the court could conflict with regulation and enforcement by the FDA or DHS, which have special competence in the area of food

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[1] The defendants initially argued in support of their demurrer that section 337(a) expressly preempted each cause of action alleged in the complaint because it expressly precluded a private right of action, but later argued in reply that the express prohibition of a private right of action in section 337(a) "creates a conflict with the FDCA." That is, defendants now rely on "conflict" rather than "express" preemption. (See discussion, *post.*)

labeling, so the action should be dismissed under the primary jurisdiction doctrine; and (3) the plaintiffs failed to allege an affirmative representation as required in order to state a cause of action under Civil Code section 1770, subdivision (a)(5), (14) or (17). The defendants also moved to strike portions of the complaint.

The trial court sustained the demurrer to each count, with leave to amend, in an order filed on January 13, 2005. The court stated in its order that an alleged violation of the FDCA cannot provide the basis for a claim under the unfair competition law because section 337(a) "*explicitly bars a private right of action,*" quoting from our opinion in *Stevens v. Superior Court* (1999) 75 Cal.App.4th 594, 606, 89 Cal.Rptr.2d 370. The order further stated that section 337(a) precludes private enforcement of the FDCA, that alleged violations of the FDCA are the sole basis for each count alleged in the complaint, and that section 337(a) therefore preempts each count. The court rejected the plaintiffs' arguments that the primary jurisdiction doctrine does not apply and concluded that the doctrine applies. The court also concluded that a claim under the CLRA must be based on an affirmative statement of fact rather than an omission, and that the plaintiffs failed to allege an affirmative statement of fact.

The plaintiffs elected not to amend their complaint, but to challenge the sustaining of the demurrer on appeal from the judgment. The court entered a judgment of dismissal with prejudice on March 4,

2005. The plaintiffs have appealed from that judgment.

CONTENTIONS

The plaintiffs contend (1) section 337(a) neither expressly nor impliedly preempts their state law causes of action; (2) the primary jurisdiction doctrine does not apply, and even if it did apply it would support only a stay rather than dismissal; (3) the complaint alleges facts sufficient to state a cause of action under the unfair competition law based on unfair, fraudulent, and unlawful business acts or practices; and (4) the undisclosed artificial coloring of farmed salmon is itself a false representation concerning its origin within the meaning of the CLRA. The defendants dispute each of these contentions and assert the arguments that they raised in the trial court.

DISCUSSION

1. *Standard of Review*

We independently review the ruling on a demurrer and determine de novo whether the pleading alleges facts sufficient to state a cause of action. (*McCall v. PacifiCare of Cal., Inc.* (2001) 25 Cal.4th 412, 415, 106 Cal.Rptr.2d 271, 21 P.3d 1189.) We assume the truth of the properly pleaded factual allegations, facts that reasonably can be inferred from those expressly pleaded, and facts of which judicial notice can be taken. (*Schifando v. City of Los*

Angeles (2003) 31 Cal.4th 1074, 1081, 6 Cal.Rptr.3d 457, 79 P.3d 569.) We construe the pleading in a reasonable manner and read the allegations in context. (*Ibid.*)

The sustaining of the demurrer also encompassed a ruling on preemption. Preemption presents a question of law concerning statutory construction and legislative intent, which we review de novo. (*Spielholz v. Superior Court* (2001) 86 Cal.App.4th 1366, 1371, 104 Cal.Rptr.2d 197.)

2. *Preemption Principles*

The supremacy clause of the United States Constitution (art. VI, cl. 2) grants Congress the power to preempt state law. (*Crosby v. National Foreign Trade Council* (2000) 530 U.S. 363, 372, 120 S.Ct. 2288, 147 L.Ed.2d 352.) Federal preemption is a question of congressional intent. (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700; *English v. General Electric Co.* (1990) 496 U.S. 72, 78-79, 110 S.Ct. 2270, 110 L.Ed.2d 65.) Particularly in a field traditionally occupied by the states such as the exercise of a state's police powers, Congress's intent to preempt state law must be "clear and manifest." (*Medtronic, supra,* at p. 485, 116 S.Ct. 2240.) Consumer protection laws such as the unfair competition law, false advertising law, and CLRA, are within the states' historic police powers and therefore are subject to the presumption against preemption. (*Washington Mutual Bank v. Superior Court* (2002) 95

Cal.App.4th 606, 613, 115 Cal.Rptr.2d 765; *Black v. Financial Freedom Senior Funding Corp.* (2001) 92 Cal.App.4th 917, 926, 112 Cal.Rptr.2d 445.) That presumption applies not only to the question of whether Congress intended to preempt state law, but also to the scope of preemption. (*Medtronic, supra,* 518 U.S. at p. 485, 116 S.Ct. 2240) The party asserting that a federal law preempts a state law bears the burden to demonstrate preemption. (*Bronco Wine Co. v. Jolly* (2004) 33 Cal.4th 943, 956, 17 Cal.Rptr.3d 180, 95 P.3d 422.)

Congress's intent to preempt state law may be stated expressly, or it may be implied if a federal law demonstrates an intent to "occupy the field" or a state law conflicts with a federal law. (*Crosby v. National Foreign Trade Council, supra,* 530 U.S. at p. 372, 120 S.Ct. 2288.) The existence of an express preemption clause implies that Congress did not intend to preempt other matters, but does not necessarily negate the possibility of field or conflict preemption. (*Sprietsma v. Mercury Marine* (2002) 537 U.S. 51, 64-65, 123 S.Ct. 518, 154 L.Ed.2d 466; *Freightliner Corp. v. Myrick* (1995) 514 U.S. 280, 288, 115 S.Ct. 1483, 131 L.Ed.2d 385.) Congressional intent to occupy the field "may be inferred from a 'scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,' or where an Act of Congress 'touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same

subject.' [Citation.]" (*English v. General Electric Co., supra,* 496 U.S. at p. 79, 110 S.Ct. 2270.) In a field "'traditionally occupied by the States,' congressional intent to supersede state laws [by occupying the field] must be '"clear and manifest."' [Citation.]" (*Ibid.*) Conflict preemption exists where state law conflicts with federal law so that compliance with both the state and federal laws is impossible, or where the state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" (*Crosby, supra,* at p. 373, 120 S.Ct. 2288.) Again, the presumption against preemption applies in a field traditionally occupied by the states, so conflict preemption must be clear and manifest. (*Bronco Wine Co. v. Jolly, supra,* 33 Cal.4th at p. 958, fn. 12, 17 Cal.Rptr.3d 180, 95 P.3d 422.)

3. *Section 337(a) Preempts Each Count Alleged in the Complaint*

The FDCA prohibits, among other things, the misbranding of food in interstate commerce. (21 U.S.C. § 331(b).) A food is considered misbranded if "its labeling is false or misleading in any particular" (*id.*, § 343(a)) or "it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with this paragraph is impracticable" (*id.*, § 343(k)). A federal district court may enjoin a violation of section 331 and in some cases may impose criminal penalties, and the offending food article may be seized. (*Id.*, §§ 332, 333(a) &

(d), 334.) A proceeding to enforce the FDCA or to restrain a violation must be commenced by and in the name of the United States, except that a state may commence a proceeding for the civil enforcement of, or to restrain a violation of, certain provisions after giving notice to the federal government. (*Id.*,§ 337(a) & (b).)[2]

Section 337(a) does not *expressly* state that state laws are preempted, but states that an action to enforce the FDCA must be by and in the name of the United States. Section 337(a) thus precludes a private right of action to enforce the FDCA. (*Pacific Trading Co. v. Wilson & Co., Inc.* (7th Cir.1976) 547 F.2d 367, 370; *see Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 349, fn. 4, 352, 121 S.Ct. 1012, 148 L.Ed.2d 854.) As the United States Supreme Court stated in *Buckman,* section 337(a) is "clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government." (*Buckman, supra,* at p. 352, 121 S.Ct. 1012.)

The Sherman Law also prohibits the misbranding of food (Health & Saf.Code, § 110765) in language

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[2] "Except as provided in subsection (b) of this section [describing the limited circumstances where a state government may prosecute an action to enforce or restrain violations of the FDCA and the conditions imposed thereon], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. . . ." (21 U.S.C. § 337(a).)

that parallels that of the FDCA. A food is considered misbranded if "its labeling is false or misleading in any particular" (*id.*, § 110660) or "it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless its labeling states that fact" (*id.*, § 110740). The Sherman Law also states that "[a]ll food labeling regulations" adopted pursuant to the FDCA "shall be the food labeling regulations of this state" and that the DHS may adopt additional regulations. (Health & Saf.Code, § 110100, subds. (a) & (b).) The DHS may issue a complaint to impose a civil penalty against any person charged with a violation of the Sherman Law or its implementing regulations, that person is entitled to an administrative hearing conducted pursuant to the administrative adjudication provisions of the Administrative Procedures Act (Gov.Code, § 11400 et seq.), and the decision of the DHS is subject to judicial review. (Health & Saf.Code, §§ 111855, 100171.) The Sherman Law states that the DHS or any other person also may commence an action in the superior court for an injunction to restrain a violation of the Sherman Law. (*Id.*, §§ 111900, 111910.) If the action is brought by the Attorney General or a district attorney, the court may impose a civil penalty. (*Id.*, § 111915.)

In section 337(a), Congress clearly expressed its intention to preclude private enforcement of the FDCA. By providing that only the federal government and, in some limited circumstances and only after giving notice to the federal government, a state may commence an action to enforce the FDCA, Congress

reserved for the federal government and the states the discretion to enforce or not enforce the FDCA in any particular set of circumstances and afforded the federal government a degree of oversight of the enforcement of the act. To allow a private person to prosecute a state law private right of action *based on a violation of the FDCA* would interfere with that governmental prosecutorial discretion and federal government oversight and conflict with the clear congressional intent to provide for a comprehensive and exclusive governmental enforcement scheme. These circumstances seem to demonstrate that a state law private right of action based on a violation of the FDCA necessarily would conflict with section 337(a). (*See Summit Technology v. High-Line Medical Instruments* (C.D.Cal.1996) 922 F.Supp. 299, 306, 316 [claims under California's unfair competition law and false advertising law based on conduct that violated the FDCA were "an attempt to assert a private right of action where none exists"]; *Animal Legal Defense Fund v. Provimi Veal Corp.* (D.Mass.1986) 626 F.Supp. 278, 283 [state law claims based on violations of the FDCA and a parallel Massachusetts statute were preempted because the FDCA precludes a private right of action].)

We reject the Attorney General's argument that section 337(a) only restricts standing in an action to "*directly* enforce" the FDCA. In our view, by precluding a private right of action "for the enforcement, or to restrain violations, of this chapter," section 337(a) necessarily "conflicts" with any private state law

cause of action that is *based on a violation of the FDCA.*

The plaintiffs' count for violation of the unfair competition law is clearly predicated on alleged violations of the FDCA and the Sherman Law. The "unlawful" prong of the unfair competition law authorizes a cause of action based on a violation of another statute even if there is no private right of action under the other statute. (*Stop Youth Addiction, Inc. v. Lucky Stores, Inc.* (1998) 17 Cal.4th 553, 562, 71 Cal.Rptr.2d 731, 950 P.2d 1086.) "[I]t is in enacting the UCL itself, and not by virtue of particular predicate statutes, that the Legislature has conferred upon private plaintiffs 'specific power' [citation] to prosecute unfair competition claims." (*Ibid.*) The mere absence of a private right of action to enforce a statute therefore does not preclude a right of action under the unfair competition law based on a violation of the predicate statute.

Federal preemption, however, is another question. A private right of action under the unfair competition law based on an alleged violation of the FDCA or the parallel provisions of the Sherman Law would conflict with the clear congressional intent to preclude private enforcement of the federal act. In our view, if the alleged conduct would constitute a violation of the FDCA, a private right of action under the unfair competition law challenging the same conduct would interfere with the exclusive prosecutorial discretion of the federal and state governments with respect to FDCA violations, frustrate the federal

government's oversight of the act's enforcement, and conflict with the clear congressional intent to preclude a private right of action based on an FDCA violation.

The plaintiffs allege in their operative complaint that the defendants have failed to disclose that farmed salmon offered for sale was artificially colored by use of canthaxanthin and astaxanthin in the fish feed, in violation of the FDCA and the Sherman Law, and that the same conduct also constitutes unfair and unlawful business acts and practices under the unfair competition law, unfair or deceptive trade practices under the CLRA, false and misleading advertising in violation of the false advertising law, and negligent misrepresentation. Put somewhat differently, the plaintiffs rely upon, and in order to recover under any count in their complaint would necessarily have to prove, facts reflecting one or more violations of the FDCA. This is true even though, as the Attorney General emphasizes, the plaintiffs are actually seeking recovery under the provisions of state law. The Attorney General argues that such allegations constitute a permissible "indirect" enforcement of the federal act that is not subject to preemption. The critical issue, however, is not whether the plaintiffs' complaint is seeking "direct" or "indirect" enforcement of the federal act, but whether the defendants' conduct upon which the plaintiffs' claims rest involves violations of the FDCA that the plaintiffs will necessarily have to prove in order to recover under their state law claims. Thus, the proper standard to be

applied rests upon what facts the plaintiffs will be required to prove under the allegations of their complaint. If those facts demonstrate violations of the FDCA, then preemption will apply irrespective of the particular state law theories of recovery relied upon by the plaintiffs. To hold otherwise would sanction a patent evasion of section 337(a) and would permit the plaintiffs to do the very thing that adherence to federal law would preclude.

We therefore conclude that all of the plaintiffs' state law causes of action are preempted. The plaintiffs allege no factual basis for any of their causes of action apart from the alleged conduct of the defendants which, if true, would violate one or more provisions of the FDCA. As a result, those causes of action are all preempted.[3] Thus, the trial court's sustaining of the demurrer to each count was proper based on preemption. Accordingly, we need not reach or consider the other grounds relied upon [sic] the court.

DISPOSITION

The judgment is affirmed. The defendants are entitled to recover their costs on appeal.

KLEIN, P.J., and ALDRICH, J., concur.

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[3] The plaintiffs acknowledge that their state law claims "incorporate and/or parallel federal food labeling standards."

SUPERIOR COURT OF THE
STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

COORDINATED PROCEEDING SPECIAL TITLE (RULE 1550(B))	JCCP 4329
FARM RAISED SALMON CASES	**ORDER SUSTAINING JOINT DEMURRER WITH LEAVE TO AMEND**
JENNIFER KANTER, et al., Plaintiffs, vs. SAFEWAY INC., et al., Defendants.	(Filed Jan. 13, 2005)

The Defendants' Joint Demurrer to the Consolidated Amended Complaint and the Joint Motion to Strike Portions of the Consolidated Amended Complaint came on regularly for hearing on November 29, 2004 at 2:00 PM in Department 309 of the above-entitled court, the Honorable Anthony J. Mohr, Judge Presiding. Jay W. Connolly of Seyfarth Shaw, LLP, Allan B. Cooper of Ervin, Cohen & Jessup, LLP, Michael L. Coates of Streeter & Nangano, Norman H. Levine of Greenberg, Glusker, Fields, et al., Paul W. Davies of O'Melveny and Meyers, LLP and David C. Allen of Akin Gump Strauss Hauer & Feld, LLP appeared on behalf of the Defendants. Kevin Roddy

and Elaine T. Byszewski of Hagens Berman appeared on behalf of Plaintiffs.

BACKGROUND

In these coordinated actions, Plaintiffs claim Defendants sell farm-raised salmon without disclosing that the feed on which the salmon were raised contained the color additives canthaxanthin and/or astaxanthin. The Complaint alleges four causes of action: (1) unfair competition in violation of Business and Professions Code ("B & P") §17200; (2) violation of the Consumer Legal Remedies Act ("CLRA"), Civil Code § 1770(a); (3) violation of B & P §17500; and (4) negligent misrepresentation.

Each of Plaintiffs' claims seeks relief based on Defendants' alleged violations of the federal Food, Drug and Cosmetic Act ("FDCA"), the United States Food and Drug Administration's (FDA) color additive regulations promulgated thereunder, and Defendants' alleged violations of California's Sherman Food, Drug, and Cosmetic Laws ("The Sherman Laws").[1] The California Sherman Laws adopt the FDA's color

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[1] The Sherman Laws incorporate by reference all color additive regulations promulgated by the FDA pursuant to the FDCA. *See* Health and Safety Code § 110090 ("All color additive regulations and any amendments to the regulations adopted pursuant to the federal act in effect on November 23, 1970, or adopted on or after that date, are the color additive regulations of this state.").

additive regulations *in toto* without any amendments at all.

Defendants allegedly failed to comply with the FDA regulations by not labeling farm-raised salmon sold in their stores with the phrase "color added," or some similar wording. Plaintiffs further aver that had Defendants complied with the FDA's labeling requirements, Plaintiffs and the putative class members would not have purchased the farm-raised fish.

DISCUSSION

The California Laws on which Plaintiffs Rely are Preempted

In *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 17 Cal. 4th 553 (1998), the California Supreme Court held that our Unfair Competition Law "cannot be used to state a cause of action the gist of which is absolutely barred under some other principle of law." 17 Cal. 4th at 566. Based on *Stop Youth Addiction*, the Court of Appeal has observed that "the UC[L] allows ***nearly*** any law or regulation to serve as its basis ***unless the predicate statute explicitly bars a private right of action***, or the defendant is otherwise privileged or immune." *Stevens v. Superior Court*, 75 Cal. App. 4th 594, 603-04, 606 (1999). This suggests that if the FDCA prohibits private litigants from suing over noncompliance with the FDA's regulations, then Plaintiffs' UCL claim cannot borrow violations of the FDCA and its attendant regulations.

Section 337(a) of the FDCA states: "Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). The United States Supreme Court has stated that the FDCA "leaves no doubt that it is the Federal Government rather than private litigants" who are authorized to file suit for noncompliance with the FDA's regulations. *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4. (2001), *citing* 21 U.S.C. § 337(a). Thus, pursuant to 21 U.S.C. § 337(a) and *Buckman*, and following the principles set forth in *Lucky Stores* and *Stevens*, the UCL cannot borrow violations of the FDCA or the FDA's regulations on food labeling promulgated thereunder.

The only exception to exclusive federal prosecution of FDA regulations is found in subsection (b)(1) of section 337: "A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State." However, the State may commence such an action only after giving the Secretary of Health & Human Services 30 days notice, during which the federal government may decide to commence its own action. 21 U.S.C. § 337(b)(2). No provision of law allows a private citizen to commence such an action, with or without notice to the federal authorities.

Even the exception set forth in section 337(b)(1) does not apply here. Section 343(m) deals with color additives, the subject matter of Health & Safety Code Section 110090, and it is not one of the exceptions to the federal enforcement exclusivity provision in Section 337(b)(1). Plaintiffs do not allege any independent common law or statutory duty to label farm-raised salmon as containing color additives other than what the FDA regulations contain. Resolution of each of Plaintiffs' causes of action will therefore turn on the FDA's regulations. In light of the prohibition against private suits to enforce the FDA's regulations, Plaintiffs' suit is barred.

Plaintiffs rely principally on *People v. McKale*, 25 Cal. 3d 626 (1979) and *Samura v. Kaiser Foundation Health Plan, Inc.*, 17 Cal. App. 4th 1284 (1993) to argue that "it is entirely permissible for a UCL claim to be based upon violations of an underlying state or federal statute (such as the FDCA) that does not permit private claims." The Court agrees with this proposition as a general statement of the law. However, cases like McKale support the *Stop Youth Addiction/Stevens* exception: that any law may serve as the predicate for a UCL claim "*unless the predicate statute explicitly bars a private right of action.*" *Stevens*, 75 Cal. App. 4th at 606. Any private action under the UCL that seeks to borrow FDCA standards is barred by § 337(a) of the FDCA. Accordingly, Plaintiffs cannot rely on cases that permit a UCL action merely because the tethered statute or regulation is silent absent a private right of action.

McKale and *Samura* are distinguishable on two other grounds. First, *McKale* held that the "lack of express authorization for a district attorney to prosecute violations of the Mobilehome Parks Act does not preclude prosecution of an action pursuant to applicable Business and Professions Code sections for unfair competition." 25 Cal. 3d at 633. *McKale* did not address the standing provision at issue in this case: the language of UCL section 17204 that empowers *private citizens* (as opposed to law enforcement officials) to seek injunctive relief for acts of unfair competition. That a district attorney may use the UCL to enforce a law he does not have the express authority to enforce (i.e., where the statute is silent regarding enforcement authority) does not mean that private plaintiffs have the same power under § 17204.

Second, the *Samura* court cautioned that "the courts cannot assume general regulatory powers over [defendants] through the guise of enforcing Business and Professions Code section 17200." *Samura*, 17 Cal. App. 4th at 1301-1302. The FDA and the DHS have specialized knowledge in the area of food labeling that is far beyond the expertise of the general public and (at least with respect to this judge) the bench.

Plaintiffs also rely on *Medtronic v. Lohr*, 518 U.S. 470 (1996), and two California cases that interpreted *Medtronic* to circumvent Congress' express prohibition of private attempts to enforce the FDCA and its implementing regulations. *Consumer Justice Center v. Olympian Labs Inc.*, 99 Cal. App. 4th 1056 (2002) and *Washington Mutual Bank v. Superior Court*, 75

Cal. App. 4th 773 (1999). Plaintiffs' argument fails to distinguish express preemption, which was the subject of *Medtronic*, from implied preemption.

The Supreme Court clarified its *Medtronic* decision in *Buckman*, *supra*, 531 U.S. 341. There, patients claiming to have suffered injuries from orthopedic bone screws in their spines brought suit alleging that a consultant to the bone screw manufacturer made fraudulent representations to the FDA in the course of obtaining approval to market the screws. Plaintiffs alleged that the misrepresentations played a substantial role in the events causing their injuries. The trial court held that the claims were an attempt to privately enforce the FDCA and conflicted with the prohibition against private enforcement actions in § 337(a).

The Third Circuit reversed and held that plaintiffs' state law claims were neither expressly nor impliedly preempted. The Supreme Court reversed, finding that the patients' state law claims were impliedly preempted by § 337(a) of the FDCA. In so holding, the Supreme Court distinguished *Medtronic* and reasoned that a difference exists between state laws that parallel federal FDA safety requirements and those seeking to enforce the FDA's disclosure requirements. The Court stated:

> It is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, **not solely from the violation of FDCA requirements.** *See* **518 U.S., at 481,**

> **116 S.Ct. 2240. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements.** Thus, although Medtronic can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.
>
> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.
>
> *Buckman*, 531 U.S. at 352-353.

As in *Buckman*, because Plaintiffs' claims are based solely on the presence of, and the Defendants' alleged failure to comply with, the FDA's labeling regulations promulgated under the FDCA, Plaintiffs' state law claims are preempted. Plaintiffs' UCL claims exist mainly by virtue of the FDCA labeling disclosure requirements, which were imported wholesale into the Health and Safety Code. Resolving Plaintiffs' claims will have to turn on Defendants' compliance with the FDA's regulations.

Medtronic was a product liability case in which plaintiff suffered injuries when the Medtronic pacemaker implanted in her heart failed. The trial court granted summary judgment to Medtronic based on §360k(a) of the MDA, which Congress expressed its intent to preempt certain state laws. *See* FDCA, 21 U.S.C. § 360k(a). The case at bar does not involve § 360k, which does not apply to food. The FDA's regulations occupy the field with regard to food labeling, including farm-raised salmon. In the area of medical devices, Congress left it to the FDA to define the scope of the preemptive effect of the MDA. This is not true for food regulation or § 337(a) of the FDCA. The FDA has not been granted the authority to define the preemptive effect of § 337(a). As such, the Supreme Court's analysis of § 360k(a) and (b) in *Medtronic* is inapplicable to the preemption issues presented by this demurrer.

Plaintiffs Fail to Allege a Private Right of Action Under The Sherman Laws

Health and Safety Code § 110090 adopts all of the FDA's color additive regulations that were promulgated pursuant to the FDCA, including those dealing with canthaxanthin and astaxanthin farm-raised salmon.[2] California incorporated the FDA's

[2] Pursuant to Health and Safety Code §110090, all color additive regulations adopted by FDA pursuant to the "federal act" are regulations of the State of California. The "federal act" is the FDCA. *See* Health and Safety Code § 109930.

regulations by reference *in toto*, without modification or amendment.

Plaintiffs fail to allege a private right of action under the Sherman Laws. First, just as the federal statute allows actions to be filed only by the federal government, 21 U.S.C. § 337(a), the state legislation left enforcement solely to the Attorney General, district attorneys and city attorneys. Health & Safety Code § 111840. Second, since the federal law precludes private enforcement, the enactment of an analogous state provision without specific reference to a private right of action reflects a legislative intention to follow federal law. "We must presume that when the Legislature enacted the ALRA, it was aware that the courts, not the National Labor Relations Board, adjudicated alleged violations of section 186." *United Farm Workers of America, AFL-CIO v. Dutra Farms*, 83 Cal.App.4th 1146, (2000). "When a state statute is modeled on a federal statute we presume the Legislature intended to adopt the construction employed by the federal courts." *In re M.S.*, 10 Cal.4th 698 (1995) *citing People v. Simon*, 9 Cal.4th 493, 511 (1995) and *Los Angeles Met. Transit Authority v. Brotherhood of Railroad Trainmen*, 54 Cal.2d 684, 688-689 (1960).

This court cannot find a case permitting private enforcement of Section 110090 or any of the similar Health & Safety Code provisions that incorporate federal regulations. The only case to address the issue, *Summit Technology v. High-Line Medical Instruments Co., Inc.*, 922 F. Supp. 299 (C.D. Cal.

1996) ("*Summit I*"), held that no private right of action is available under the Health & Safety Code.

Plaintiffs Fail to Allege an Action under Penal Code § 383

Plaintiffs also attempt to tether a section 17200 violation to what appears to be a sleeping statute, Penal Code § 383. To the extent that the language of Penal Code § 383 makes the use of FDA-approved color additives unlawful, it similarly is preempted by federal law. Adopted in 1872, this section makes it a crime to sell any adulterated food. Adulterated food is defined to include any food that is colored to enhance its appearance or value. The statute makes no exceptions for foods colored with color additives approved by the FDA for use in food. A violation occurs whether or not the presence of the color additive is disclosed. The scope of Penal Code § 383 arguably criminalizes the use of an FDA-approved color additive.

This conflict resembles that addressed in *Kanter v. Warner-Lambert Co.*, 99 Cal.App.4th 780, 796 (2002). Plaintiffs brought state law claims against a manufacturer of an over-the-counter treatment for head lice for allegedly false and misleading statements on the manufacturer's label. The FDA had approved the use of the label in question. *Id.* at 787. The Court held that to the extent the theories of liability under California state law outlawed or banned what the FDA allowed, the state law claims were preempted. Specifically, the Court held:

> While the legal theories underlying these causes of action may differ, each is bottomed on the assertion that this approved label is no longer accurate or adequate and that the label should be changed or the product banned. Each cause of action would result in the establishment of a state requirement regarding labeling that would be "different from" and "otherwise not identical with" the federally required label (Sec. 379r(a)), and each is therefore preempted. *Id.*

While *Kanter* dealt with a different section of the FDCA, it stands for the proposition that state law cannot create civil liability for use of products the FDA permits. Here Penal Code § 383 is preempted to the extent that it conflicts with the FDA regulations allowing the color enhancement of food.

The Primary Jurisdiction Doctrine

Plaintiffs oppose the primary jurisdiction of the FDA and the DHS by arguing that the primary jurisdiction doctrine does not apply because there are no "pending or anticipated administrative procedures concerning required disclosure standards for farm-raised salmon." *AICCO, Inc. v. Ins. Co. of North America*, 90 Cal. App. 4th 579, 594 (2001) did not decline to apply the primary jurisdiction doctrine because no pending or anticipated administrative procedure existed. Rather, the court declined to apply the doctrine because "the administrative bodies have already rendered whatever decision might be relevant

to the present suit [accordingly], there was no need to stay the action for further action by some administrative body." *AICCO*, 90 Cal. App. 4th at 594-595. The court declined because *there was no need for further recourse to those agencies*. Here, the FDA has already regulated labeling for the color additives at issue and has stated its intention with respect to mislabeling of color additives. *See* 21 C.F.R. §71.22

Plaintiffs Have Not Pleaded a Violation of the Consumer Legal Remedies Act

To violate the CLRA provisions on which Plaintiffs rely, one needs an affirmative statement of fact about a product or service, not mere omissions. Plaintiffs have failed to sufficiently plead that the Defendants made affirmative false statements.

Relying on *Saunders v. Superior Court*, 27 Cal. App. 4th 832 (1994) and *Motors, Inc., v. Times-Mirror Co.*, 102 Cal. App. 3d 735 (1980), plaintiffs argue that whether a defendant's actions amount to affirmative conduct is "a question of fact not properly resolved by demurrer." Neither *Saunders* nor *Motors, Inc.* includes any analysis of whether the alleged wrongdoing in those cases constituted an affirmative representation or merely an omission.

Plaintiffs cite *Outboard Marine Corp. v. Superior Court*, 52 Cal. App. 3d 30 (1975), for the proposition that the CLRA draws no distinction between affirmative representations and mere omissions. *Outboard Marine* cannot be read to support Plaintiffs' argument.

The seller of an all-terrain vehicle affirmatively represented certain performance specifications that the vehicle would achieve when driven in off-road areas. The purchaser brought an action because the vehicle failed to meet the affirmative representations. The purchaser pled two causes of action. One alleged that the seller's affirmative statements were false. The second alleged that the seller concealed the fact that the vehicle did not have the characteristics described in the seller's affirmative statements. The "concealment" cause of action was in essence the flip side of the affirmative misrepresentation cause of action. 52 Cal. App. 3d at 36-37. Based on the proposition that "[i]t is fundamental that every affirmative misrepresentation of fact works a concealment of the true fact," the *Outboard Marine* Court explained that the two causes of action allege, in different language, identical conduct. *Id.* By contrast, Plaintiffs' allegations of non-disclosure constitute the gravamen of the Complaint at bar.

CONCLUSION AND ORDER

The Joint Demurrer is SUSTAINED. The court doubts that the plaintiffs will be able to amend to state a cause of action. However, this not a situation in which the plaintiffs have already filed a number of amended complaints. In an abundance of caution, the

court will give plaintiffs 30 days leave to amend. The motion to strike is moot and taken off calendar.

Dated JAN 13 2005

ANTHONY J. MOHR
Anthony J. Mohr
Judge of the Superior Court

H.R. 3562, 101st Cong., 2d Sess. (1990)

UNITED STATES [SEAL] OF AMERICA

Congressional Record

PROCEEDINGS AND DEBATES OF THE *101st* CONGRESS
SECOND SESSION

VOLUME 136 – PART 14

JULY 26, 1990 TO JULY 31, 1990

(PAGES 19491 TO 20963)

* * *

The SPEAKER, pro tempore. The gentleman from California [Mr. WAXMAN] will be recognized for 20 minutes, and the gentleman from Illinois [Mr. MADIGAN] will be recognized for 20 minutes.

The Chair recognizes the gentleman from California [Mr. WAXMAN].

GENERAL LEAVE

Mr. WAXMAN, Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks on H.R. 3562, the bill now under consideration.

The SPEAKER, pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. WAXMAN, Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, the purpose of this legislation is to make sense of the confusing array of nutrition labels that confront all consumers every time they enter the supermarket.

H.R. 3562 would require that food products disclose their nutritional content. Every food that is covered would have a uniform nutrition label that would disclose the amount of calories, fat, salt, and other nutrients. Where full labeling would be impractical, the bill provides for an exemption or requires that the information be provided in a modified form. Under this principle, restaurants are exempt from the nutrition labeling requirements. The information pertinent to fish, fruits, and vegetables would be conveyed by a sign or brochure made available at the supermarket, rather than by labeling on the food.

The bill also addresses the issue of nutrition claims on foods. First, content claims would have to be consistent with terms defined by the Secretary of the Department of Health and Human Services, who would presumably delegate this authority to the Commissioner of the Food and Drug Administration. Today, companies use terms such as "low" and "light" differently and inconsistently. On some products, "light" means low in fat; on others, such as some brands of olive oil, it refers to the color of the product. The bill would correct this deceptive and misleading state of affairs by requiring that terms such as "light" have a single meaning.

The second issue concerns disease claims. Today, a variety of disease claims are made on foods. An example would be the claim that bran prevents cancer. Under this bill, before such a claim could be made, the FDA would review the scientific evidence and decide whether the claim is valid. Once the FDA decides that a specific claim is valid, then any company could make a claim that was consistent with the FDA's findings.

Mr. Speaker, the bill before us has been substantially changed since it was reported by the Committee on Energy and Commerce. Those changes reflect negotiations between the committee and interested parties in the private sector. The legislative intent of those negotiations is reflected in a separate statement of intent of the changes that have been made to H.R. 3562 since the bill was reported by the Energy and Commerce Committee. That statement has been reviewed by both me and by Mr. MADIGAN, and it reflects our understanding of the changes that have been made.

I would like to say a word about the changes that have been made with respect to preemption of State laws because I believe that the compromise that we have negotiated reflects principles that we should adhere to in the future when addressing similar issues.

The first principle is that State laws should not be preempted unless the nature of the laws at issue makes it difficult and even impossible for companies

to operate in interstate commerce. In the case of food labeling laws at issue with regard to H.R. 3562, the food industry made a strong argument that this was the case. A national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws. This argument, which has particular appeal with respect to food labels, would have far less appeal where other types of preemption are at issue.

Second, the States should never be preempted unless a strong Federal regulatory system is in place. Under this principle, provisions for preempting the States on nutrition labeling and health claims were included in H.R. 3562 at the time it was reported out by the Subcommittee on Energy and Commerce.

However, the bill before the Members today contains provisions that would preempt other aspects of the food label, such as provisions regarding misleading containers and the prominence of labeling. Because we were unable to determine whether the Federal standard is strong in these areas, the bill provides for a study of Federal and State standards to determine whether additional Federal regulation is needed. If additional Federal regulation is deemed necessary, then the States will not be preempted until those regulations are in place.

Third, any preemption provision must recognize the important contribution that the State can make in regulation, and it must leave a role for the states.

H.R. 3562 recognizes the importance of the State role: by allowing States to adopt standards that are identical to the Federal standard, which may be enforced in State court; by allowing the States to enforce the Federal standard in Federal court; and by allowing the States to petition for permission to enforce a separate State law where the State demonstrates a particular need and where such a law would not unduly burden interstate commerce.

Fourth, and most importantly, the most compelling argument for State regulation is where the States have adopted laws to protect the safety of their citizens. Therefore, the preemption provisions in H.R. 3562 explicitly permit the States to adopt requirements for warning about the ingredients or components of food.

As a result of these negotiations, H.R. 3652 has strong support from both the public health organizations that have been active on nutrition issues and from the trade associations of food companies that will be affected by the bill. I have received letters of support from the American Bakers Association, the Food Marketing Institute, Grocery Manufacturers of America Inc., International Ice Cream Association, Milk Industry Foundation, the National American Wholesale Grocers Association, the National Food Processors Association, the National Grocers Association as well as the American Dietetic Association, American Heart Association, American Cancer Society, American Association of Retired Persons, and the Society for Nutrition Education.

I would like to say a final word about the work behind this bill. As is true of any important piece of legislation, H.R. 3562 is the result of hard work by many Members, some of whom have had their own legislative proposals in this area, specifically Mr. COOPER, Mr. SLATTERY, Mr. SMITH, and Mr. GLICKMAN.

There are two Members whose contribution I would particularly like to single out for special mention. The first is the gentleman from Massachusetts. Mr. MOAKLEY, who has championed the cause of nutrition information for many years and who introduced legislation which served as the progenitor of H.R. 3562 before our subcommittee even considered it.

The second Member I would like to thank is my friend, the gentleman from Illinois [Mr. MADIGAN], the principal cosponsor of this bill. From the time the bill was introduced, the gentleman from Illinois has worked tirelessly to ensure that the bill remains strong and that we do all we can to enact it into law. He has insisted that the bill be as effective as possible so that all Americans can be fully and fairly informed about the nutritional characteristics of the food that they eat.

Then last, I want to mention the contribution of the staff, particularly the minority staff, Mary McGrane, and our subcommittee counsel Bill Schultz.

* * *

H.R. Rep. 101-538, 101st Cong., 2d Sess. (1990)

NUTRITION LABELING AND EDUCATION ACT OF 1990

JUNE 13, 1990. –Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. DINGELL, from the Committee on Energy and Commerce, submitted the following

REPORT

[To accompany H.R. 3562]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3562) to amend the Federal Food, Drug, and Cosmetic Act to prescribe nutrition labeling for foods, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

* * *

PURPOSE AND SUMMARY

The purpose of this legislation is to clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods. The bill covers only nutrients or substances in food that "nourish,"

and it does not in any way regulate carcinogens or other, non-nutritive substances in foods.

The bill would require that food products disclose the amount of specified nutrients in foods. Every covered food would have a uniform nutrition label disclosing the amount of calories, fat, salt and other nutrients. In order to make this information meaningful, the bill requires the FDA to issue standards providing that uniform serving size information and information concerning the number of servings be furnished on the food label.

Where full labeling is impractical, the bill provides for an exemption or requires that the information be provided in a modified form. Under this approach, restaurants are exempt from the nutrition labeling requirements. The information pertinent to raw fish, fruits and vegetables would be conveyed by a sign or brochure made available at the site of sale, rather than by a label on the food.

The bill also addresses the issue of claims that may be made about nutrients in foods. First, content claims (such as "low salt" or "light") would have to be consistent with terms defined by the Secretary of Health and Human Services ("HHS").

Second, the bill provides a process for the orderly regulation of disease claims (such as "fiber prevents cancer"). Under the bill, the Food and Drug Administration ("FDA") would review the scientific evidence and decide if the claim is valid. A disease claim may not be made unless it is consistent with a final regulation

issued by the FDA. Once the FDA decides that a specific claim is valid, any company can make a claim that is consistent with the FDA's findings.

The bill also contains a provision that would prevent State and local governments from adopting inconsistent requirements with respect to the labeling of nutrients or with respect to the claims that may be made about the nutrients in foods. However, these governmental entities are explicitly permitted to enforce Federal requirements with respect to nutrition labeling.

Finally, the bill requires the FDA to issue final regulations for implementation of the nutrition labeling and claims requirements within 18 months of enactment. Individuals and companies subject to the bill's provisions would be given six additional months to comply with the requirements.

The new nutrition labeling requirements would be administered by the Secretary of Health and Human Services through the FDA. The legislation would not alter existing law with regard to the division of jurisdiction between FDA and the U.S. Department of Agriculture.

* * *

SECTION-BY-SECTION ANALYSIS AND DISCUSSION

Section 1 provides that the short title of the bill is the "Nutrition Labeling and Education Act of 1990."

* * *

SECTION 4: STATE ENFORCEMENT

States are authorized to bring actions to enforce sections 2 and 3 (which add sections 403(q) and (r) to the FFDC Act) in the name of the State if the State notifies the Secretary at least 30 days before the proceeding is brought. The proceedings would be brought in Federal court and would supplement the FDA's enforcement capabilities.

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No. 07-1327

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IN THE

Supreme Court of the United States

ALBERTSON'S, INC., ET AL.,

Petitioners,

v.

JENNIFER KANTER, ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF CALIFORNIA

BRIEF IN OPPOSITION

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STATEMENT

1. ***Plaintiffs' Allegations.*** Petitioners are large grocery store chains (hereinafter Grocery Stores). Respondents are consumers (hereinafter Plaintiffs) who allege that the Grocery Stores violated California law by failing to disclose that their farm-raised salmon was artificially colored. Plaintiffs state four causes of action: (1) violation of California's unfair competition law, Bus. & Prof. Code, § 17200 *et seq.*; (2) violation of California's Consumers Legal Remedies Act, Civ. Code, § 1750 *et seq.*; (3) violation of California's false advertising law, Bus. & Prof. Code, § 17500 *et seq.*; and (4) negligent misrepresentation under California law.

2. ***Proceedings in California Superior Court.*** Plaintiffs filed their actions in the California Superior Court. The Grocery Stores sought dismissal of Plaintiffs' consolidated complaint on the ground that § 337(a) of the FDCA preempts Plaintiffs' state law claims. The Superior Court agreed and dismissed the complaint. The Superior Court also dismissed the complaint on other grounds not at issue before this Court.

3. ***Proceedings in California Court of Appeal.*** The California Court of Appeal held that § 337(a) impliedly preempts all of Plaintiffs' claims. The Court of Appeal did not reach the other grounds for dismissal asserted by the Grocery Stores.

4. ***Proceedings in California Supreme Court.*** The California Supreme Court reversed the Court of Appeal's decision, unanimously holding that the FDCA does not preempt Plaintiffs' claims.

Relevant Federal and State Laws

a. The Supreme Court explained that § 343(k) of the FDCA requires disclosure of the use of color additives in food. Pet. App. 7-8. The Court also explained that FDA regulations permit the use of the chemical substances astaxanthin and canthaxanthin to color the flesh of salmon, but "the chemicals' presence must be declared as prescribed by the FDA . . . ." *Id.*

b. The Court next stated that Congress amended the FDCA with the Nutrition Labeling and Education Act of 1990 (Nutrition Labeling Act), Pub. L. No. 101-535 (Nov. 8, 1990), 104 Stat. 2353. The Court noted that the Nutrition Labeling Act "included an explicit preemption provision in the form of section 343-1(a) . . . ." Pet. App. 8. In particular, § 343-1(a)(3) provides that "no State or political subdivision or a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . (3) any requirement for the labeling of food of the type required by section . . . 343(k) of this title that is not identical to the requirements of such section . . . ."

The Court then explained that § 343-1 of the FDCA permits States to adopt or continue in effect labeling requirements so long as they are identical to federal requirements:

> "Although section 343-1 speaks in terms of what states may *not* do, by negative implication, section 343-1 also expresses what states *may* do, *i.e.*, states *may* establish their own requirements pertaining to the labeling

> of artificially colored food so long as their requirements are identical to those contained in the FDCA in section 343(k). (60 Fed.Reg. 57120 (Nov. 13, 1995) [under FDA regulations, 'if the State requirement is identical to Federal law, there is no issue of preemption . . .'] . . . .)"

Pet. App. 9.

c. Next, the Court stated that California's Sherman Food, Drug, and Cosmetic Law, Health & Saf. Code, § 109875 *et seq.* (hereinafter Sherman Law), prohibits the misbranding of food. Pet. App. 10. The Court explained that "the Sherman Law uses language 'identical to' section 343(k) to provide that food is misbranded 'if it bears or contains any . . . artificial coloring . . . unless its labeling states that fact.' (Health & Saf. Code § 110740.)" *Id.* The Court then noted that "California has adopted as its own the FDA regulations regarding the use of (and disclosure of the use of) astaxanthin and canthaxanthin in the feeding of farmed salmon . . . ." *Id.*

d. The Court then explained that FDCA § 337 is a "standing provision, providing that 'all such proceedings for the enforcement, or to restrain violations, *of* [*the FDCA*] shall be by and in the name of the United States . . . .'" Pet. App. 11. The Court explained that § 337 "precludes private enforcement of the FDCA . . . and limits the circumstances under which states may seek to enforce the FDCA in federal court (§ 337(b)). Whether or not section 337 also precludes private claims predicated on state law is the crux of the present litigation . . . ." *Id.*

Presumption Against Preemption

e. The Court next noted that a "strong presumption against preemption" applies. Pet. App. 12. The Court stated that "[t]here can be no doubt that the presumption applies with particular force here . . . . Indeed, as early as the 1860's, California was enacting laws regulating food marketing." *Id.* at 13-14.

Rejection of Grocery Stores' Preemption Argument

f. The Court then explained that § 343-1 of the FDCA undermines the Grocery Stores' preemption argument. As the Court stated, the "words of section 343-1 clearly and unmistakably evince Congress's intent to authorize states to establish laws that are 'identical to' federal law." Pet. App. 17. The Court stated that

> "[i]f Congress intended to permit states to enact identical laws on the one hand, but preclude states from providing private remedies for violations of those laws on the other hand, 'its failure even to hint at it is spectacularly odd.' (*Medtronic, supra*, 518 U.S. at p. 491 (plur. opn. of Stevens, J.).)"

Pet. App. 19.

The Court then explained that the Nutrition Labeling Act (also known as the NLEA) includes a preemption provision:

> "Congress made clear that the preemptive scope of section 343-1 was to sweep no further

> than the plain language of the statute itself. In NLEA section 6(c)(1) (an uncodified provision), Congress provided that '[t]he [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [section 343-1] of the [FDCA].' (Pub.L. No. 101-535, § 6(c)(1) (Nov. 8, 1990), 104 Stat. 2364.) Thus, Congress's decision not to expressly supplant private claims based on those state laws authorized by section 343-1 should be interpreted as its considered decision to continue to allow states to provide such private remedies."

Pet. App. 20.

g. The Court further explained that two decisions by this Court mandate the conclusion that § 343-1 permits Plaintiffs' action. Pet. App. 27. The Court first discussed *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which this Court addressed the preemptive effect of § 360k(a) of the FDCA, under which "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – [¶] (1) which is different from, or in addition to, any requirement applicable under this chapter to the device . . . ." The California Supreme Court noted that in *Medtronic*, this Court "concluded that Congress did not intend to preempt 'state rules that merely duplicate some or all of [the] federal requirements.' (*Medtronic, supra*, at p. 492.) The high court further reasoned that because Congress authorized states to adopt identical requirements,

states were also free to provide for private remedies for violations of those requirements." Pet. App. 25.

The California Supreme Court then discussed *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005), in which this Court held that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) does not preempt "tort claims that parallel FIFRA's misbranding requirements." The Supreme Court of California noted that

> "[l]ike the provision at issue in *Medtronic*, FIFRA contains a preemption provision similar to section 343-1, which provides that states 'shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter' (7 U.S.C. § 136v(b); *see Bates, supra*, 544 U.S. at p. 436)."

Pet. App. 26. The Court further explained that "although FIFRA did not provide a federal remedy to the plaintiffs [for misbranding], the high court concluded that 'nothing in [7 U.S.C.] § 136v(b) precludes States from providing such a remedy.' (*Bates, supra*, 544 U.S. at p. 448.)" Pet. App. 26-27.

The California Supreme Court then reached the following conclusion regarding § 343-1:

> "[I]n light of the plain statutory language of section 343-1, and the high court's construction of similar preemption language, we conclude that Congress intended to allow

> states to establish their own requirements so long as they are identical to those contained in section 343(k), which California has done in the form of the Sherman Law. We further conclude that nothing in the text of section 343-1 or its legislative history supports the assertion that Congress intended to limit the scope of remedies states might choose to provide for the violations of those state laws."

Pet. App. 27.

h. The Court then rejected the argument by the Grocery Stores that § 337 impliedly preempts Plaintiffs' claims. The Court first established that the premise of the Grocery Stores' argument is invalid. The Court stated:

> "The crux of defendants' preemption argument is that plaintiffs' private state claims are precluded because they improperly seek to enforce the FDCA in violation of section 337(a). Defendants' starting assumption is incorrect. Plaintiffs do not seek to enforce the FDCA; rather, their deceptive marketing claims are predicated on violations of obligations imposed by the Sherman Law, something that state law undisputedly allows . . . ."

Pet. App. 28.

The Court then explained that Plaintiffs do not seek to enforce the FDCA:

> "That the Sherman Law imposes obligations identical to those imposed by the FDCA, as it must under section 343-1, does not substantively transform plaintiffs' action into one seeking to enforce federal law. Rather, it merely reflects Congress's considered judgment that states should uniformly regulate food labeling using identical standards. Indeed, while the high court in *Medtronic* did not expressly consider the impact of section 337 on the private state action at issue there, it held that those plaintiffs' private actions were permitted *because* they were identical to the FDCA. (*Medtronic, supra*, 518 U.S. at p. 495.) It is difficult to believe the high court would have so held if section 337 expressed a "'clear and manifest'" intent (*Medtronic*, at p. 485) to preclude private actions based on state laws explicitly authorized by the FDCA in section 343-1."

Pet. App. 28-29.

As a result, the California Supreme Court held that "[s]ection 337 does not apply to the state law claims presented here. The statute, by its very terms, only implicates efforts to enforce *federal* law. What section 337 does *not* do is limit, prohibit, or affect private claims predicated on *state* laws." Pet. App. 29.

i. Having rejected the Grocery Stores' arguments, the Court reversed the judgment of the Court of Appeal. The Grocery Stores now ask this Court to grant their petition for a writ of certiorari.

REASONS FOR DENYING THE PETITION

The Petition should be denied. First, the question presented by the Grocery Stores is not at issue in this case. The Grocery Stores contend that the question for this Court is whether Plaintiffs may enforce FDCA requirements, even though Plaintiffs seek only to enforce state law requirements, as the California Supreme Court recognized. Second, the decision by the California Supreme Court (hereinafter Decision) does not conflict with any of this Court's precedents. To the contrary, consistent with this Court's decisions, the California Supreme Court held that private citizens may sue to enforce state labeling requirements that are identical to FDCA requirements. Third, the Decision does not conflict with any decision of another state court of last resort or United States court of appeals.

A. The Question Presented By The Grocery Stores Is Not At Issue, Because Plaintiffs Do Not Seek To Enforce The FDCA Or Any FDA Regulation.

The question presented by the Grocery Stores is not at issue in this litigation. The question presented by the Grocery Stores is whether "private parties' state law claims to enforce FDCA requirements [are] preempted by Congress' mandate that the Act be enforced only by the federal or state governments." Petition at p. i. The Grocery Stores base that question

on the incorrect premise that the California Supreme Court "held that Respondents, private citizens, could bring a class action to enforce the FDCA under the aegis of state law." *Id.* To the contrary, the Court recognized that "plaintiffs do not seek to enforce the FDCA. Their action is based on the violation of *state law* – albeit state law that is, in compliance with section 343-1, identical to FDCA provisions." Pet. App. 24. Therefore, the Court did not address, and had no reason to address, whether Plaintiffs can sue to enforce the FDCA.

Moreover, the preemption issue decided by the California Supreme Court is not fairly included in the question presented by the Grocery Stores. Supreme Court Rule 14.1(a) states that "[o]nly the questions set out in the petition, or fairly included therein, will be considered by the Court." In *Yee v. City of Escondido*, 503 U.S. 519 (1992), this Court declined to consider a question that was not fairly included in the question presented. As this Court explained,

> "Whether or not the ordinance effects a regulatory taking is a question *related* to the one petitioners presented, and perhaps *complementary* to the one petitioners presented, but it is not 'fairly included therein.' Consideration of whether a regulatory taking occurred would not assist in resolving whether a physical taking occurred as well; neither of the two questions is subsidiary to the other."

Id. at 537. Therefore, this Court held that Rule 14.1(a) barred consideration of the regulatory taking question. *Id.* at 521.

Similarly, the preemption issue decided by the California Supreme Court is not fairly included in the question presented by the Grocery Stores to this Court. Specifically, consideration of whether Plaintiffs' state law claims to enforce state laws are preempted would not assist in resolving whether private parties may sue to enforce FDCA requirements. Conversely, deciding the question presented by the Grocery Stores would be an academic exercise, because it would not resolve whether Plaintiffs may sue under state law based on state labeling requirements. Thus, review is not warranted.

B. The Decision Correctly Follows This Court's Precedents.

1. Section 337 Does Not Show That Congress Clearly And Manifestly Intended To Preempt Plaintiffs' State-Law Remedies.

Even assuming that the Grocery Stores presented the correct preemption issue to this Court, the Petition should be denied. The Grocery Stores argue that § 337, which bars private rights of action to enforce the FDCA, also impliedly preempts all private actions to enforce state requirements that parallel FDCA requirements. That argument overlooks the presumption that the FDCA does not preempt historic police powers of the States unless that was the clear and manifest purpose of Congress. *See Medtronic*, 518 U.S. at 485. Laws regulating the marketing of food are within States' historic police powers. *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144 (1963) ("States have always possessed a legitimate interest in 'the

protection of . . . [their] people against fraud and deception in the sale of food products' at retail markets within their borders.") (internal citation omitted). Therefore, the presumption applies.

Moreover, § 337 does not clearly and manifestly indicate that Congress intended the FDCA to preempt all private actions to enforce state requirements that parallel FDCA requirements. To the contrary, the lack of a private right of action undermines the Grocery Stores' argument. In *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984), this Court stated that

> "there is no indication that Congress even seriously considered precluding the use of [state] remedies either when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959. This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."

Similarly, Congress' decision not to create a federal cause of action for violation of the FDCA does not demonstrate that Congress silently intended to bar private remedies for violation of parallel state laws. To the contrary, as in *Silkwood*, the lack of a private right of action under the FDCA undermines the Grocery Stores' argument that Congress silently removed all means of judicial recourse for consumers injured by illegal conduct. *Accord*, *Bates*, 544 U.S. at 448 ("although

FIFRA does not provide a federal remedy to farmers and others who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements, nothing in § 136v(b) precludes States from providing such a remedy").

2. The Decision Is Consistent With *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

The Grocery Stores erroneously argue that the Decision conflicts with this Court's holding in *Buckman*. Contrary to the Grocery Stores' argument, *Buckman* does not stand for the proposition that § 337 precludes "state law claims to enforce requirements substantively identical to federal law" (Petition at 15). Instead, this Court recognized in *Buckman* that section 337 does *not* preclude state law claims that parallel federal requirements and that predate the FDCA.

The holding in *Buckman* was far narrower than the Grocery Stores assert. The plaintiffs in *Buckman* alleged that the defendant defrauded the FDA as to the intended use of its bone screws. The plaintiffs further alleged that "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." 531 U.S. at 343. This Court held that the FDCA preempted the plaintiffs' claim. This Court first explained that "policing fraud against federal agencies is hardly a field which the States have traditionally occupied such as to warrant a presumption against finding federal pre-emption of a

state-law cause of action." *Id.* at 347 (citation and internal quotations omitted). This Court concluded that

> "were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme."

Id. at 353.

Thus, this Court did not hold that the FDCA precludes private enforcement of state requirements that predate the FDCA and that concern a field that States have traditionally occupied. Instead, this Court held that the FDCA preempted the plaintiffs' claims because: (1) the plaintiffs did not rely on traditional state requirements that predate the FDCA; (2) policing fraud on the FDA is not a field traditionally occupied by the States; and (3) the existence of federal requirements was a critical element of the plaintiffs' case.

Under *Buckman*, the FDCA does not preempt Plaintiffs' claims in this action. First, California's requirement that artificially-colored food be labeled as such predates the enactment of the FDCA. *See* 1907 California Pure Food Act, § 6 ("Food and liquor shall be deemed mislabeled or misbranded within the meaning

of this act in any of the following cases: . . . If it be labeled or branded or colored so as to deceive or mislead, or tend to deceive or mislead the purchaser . . . ."). Second, the regulation of mislabeled food is a field traditionally occupied by the States. Third, the existence of the federal requirements regarding the labeling of foods is not an element of Plaintiffs' case, let alone a critical element.

The differences between this case and *Buckman* are reflected in this Court's explanation of the differences between *Buckman* and *Medtronic*. This Court stated in *Buckman* that

> "petitioner's dealings with the FDA were prompted by the [Medical Devices Act], and the very subject matter of petitioner's statements were dictated by that statute's provisions. Accordingly — and in contrast to situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' *Medtronic*, 518 U.S. at 485 — no presumption against preemption obtains in this case."

531 U.S. at 347-48. Moreover, this Court stated:

> [T]he *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. *See* 518 U.S. at 481. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure

> requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

Id. at 352-53. Here, Plaintiffs' claims do not rest on any violation of the FDCA but instead rest on state requirements that predate the FDCA and that are within the traditional police powers of the states. Therefore, they are not preempted.

3. The Decision Properly Follows This Court's Precedents Construing Statutes That Permit States To Adopt Requirements That Parallel Federal Requirements.

This Court has held three times that statutes such as § 343-1(a)(3) permit private causes of action to enforce state requirements that parallel federal requirements. First, in *Medtronic*, this Court construed § 360k of the FDCA, which bars States from establishing standards that are "different from, or in addition to," specified federal standards. This Court held that "[n]othing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495. This Court explained that a damages remedy under state law "merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id.*

The Grocery Stores argue that this Court did not consider in *Medtronic* whether § 337 impliedly preempts state-law claims to enforce state requirements that parallel federal requirements. The Grocery Stores, however, cannot explain why this Court would hold that private remedies for the violation of parallel state laws are not preempted if Congress clearly and manifestly intended to bar such claims by means of § 337. The plain answer is that § 337 does not preempt any such claims.

Second, this Court held in *Bates* that private citizens may enforce state law duties that parallel FIFRA requirements, even though FIFRA does not provide for a private right of action. This Court discussed the preemptive effect of § 136v(b) of FIFRA, which provides that States "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." *Bates*, 544 U.S. at 431. This Court held that "a state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id.* at 447. This Court further held that § 136v(b) allows States to provide private remedies for violation of parallel state labeling requirements. *Id.* at 448. Similarly, § 343-1(a)(3) of the FDCA permits states to adopt labeling requirements that are identical to federal requirements and to provide private remedies for violation of those requirements. As a result, the Grocery Stores' implied preemption argument under § 337 misses the mark. *See Bates*, 544 U.S. at 458 ("Because we need only determine the ordinary meaning of § 136v(b), the majority rightly declines to address respondent's argument that

petitioners' claims are subject to other types of pre-emption.") (Thomas, J., concurring in part and dissenting in part).

Third, in *Riegel v. Medtronic, Inc.*, __ U.S. __, __, 128 S. Ct. 999, 1011 (2008), this Court explained that § 360k of the FDCA

> "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements. *Lohr*, 518 U.S., at 495; *see also id.*, at 513 (O'Connor, J., concurring in part and dissenting in part). The District Court in this case recognized that parallel claims would not be pre-empted . . . ."

The Grocery Stores cannot explain why this Court held in *Riegel* that parallel claims are *not* preempted if § 337 plainly preempts such claims, as the Grocery Stores argue.

C. There Is No Conflict With Any Decision Of Another State Court Of Last Resort Or Of A United States Court Of Appeals.

The Grocery Stores do not cite a single decision by a state court of last resort or of a United States court of appeals that conflicts with the decision by the California Supreme Court. None of the cases cited by the Grocery Stores holds that § 337 impliedly preempts all parallel state-law claims. To the contrary, each case involved an attempt to enforce FDCA requirements in federal court.

For example, in *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367 (7th Cir. 1976), the plaintiffs claimed that the defendants violated the FDCA. The Seventh Circuit affirmed dismissal of the claim, which was predicated on federal question jurisdiction, because the FDCA "does not provide a cause of action for private parties suing for civil damages." *Id.* at 370. The Seventh Circuit did not address whether the FDCA preempts state-law claims to enforce state requirements that parallel federal requirements.

The other cases cited by the Grocery Stores are similarly inapposite. In *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781 (3d Cir. 1999), the plaintiffs alleged a conspiracy to violate the FDCA. The court held that "[b]ecause plaintiffs here could not sue an individual defendant for an alleged violation of the FDCA, it follows that they cannot invoke the mantle of conspiracy to pursue the same cause of action against a group of defendants." *Id.* at 789-90. Similarly, in *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997), the Court stated that "Friedlander's dogged insistence that PDK's products are sold without proper FDA approval suggests — as the district court observed in the Georgia action — that Friedlander's true goal is to privately enforce alleged violations of the FDCA .... However, no such private right of action exists." *See also Bailey v. Johnson*, 48 F.3d 965, 966 (6th Cir. 1995) ("The defendants bring this interlocutory appeal of the district court's denial of their motion to dismiss for lack of federal jurisdiction. Because we conclude that Congress did not intend to create a private cause of action when it enacted the FDCA, we reverse.").

The amicus brief of Rexall Sundown, Inc., cites yet another inapposite decision by a federal court of appeals. In *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990), the plaintiff sued for false advertising under the Lanham Act. Preemption of state-law claims was not at issue. Instead, the issue was "whether a Lanham Act false labeling claim exists against a manufacturer who lists an ingredient as 'inactive' when FDA standards seem to require that such an ingredient be labeled as 'active.'" *Id.* 230. The Third Circuit explained that the

> "FDA has not found conclusively that demulcents must be labelled as active or inactive ingredients within the meaning of 21 C.F.R. § 210.3(b)(7) . . . . Thus, we are unable to conclude that Vicks's labeling of Pediatric 44's demulcents as inactive is literally false, even if Vicks concurrently claims that these ingredients enable its medicine to work the instant it is swallowed."

Id. at 230-31. As a result, "Sandoz's position would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations." *Id.* at 231.

Sandoz is inapposite for two reasons. First, it did not involve preemption. Second, there is nothing ambiguous about the federal and state regulations that require the Grocery Stores to label their farm raised salmon as artificially colored. This case has proceeded

for years without any suggestion by the Grocery Stores that either the FDA or California is reconsidering those requirements.[1]

Finally, the Grocery Stores rely on several district court decisions, even though conflicts with district court decisions provide no basis for review under Rule 10. In any event, those decisions do not conflict with the decision of the California Supreme Court. Instead, as the California Supreme Court explained, those cases "invariably deal with a party seeking to enforce (sometimes through the use of state law) the FDCA." Pet. App. 31.[2] The Court also explained that "[b]y

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[1] The amicus brief filed by The Food Marketing Institute, *et al.*, does not provide any support for the Petition. The policy reasons set out in that brief have no bearing on the question before this Court but instead should be addressed to Congress. Moreover, this Court has explained that a state-law damages remedy "merely provides another reason for [defendants] to comply with identical existing 'requirements' under federal law." *Medtronic*, 518 U.S. at 495.

[2] *See Fraker v. KFC Corp.*, 2007 U.S. Dist. Lexis 32041 (S.D. Cal. Apr. 30, 2007) (as the California Supreme Court explained below, the plaintiff in *Fraker* sought to enforce FDA food labeling regulations); *Autin v. Solvay Pharms., Inc.* 2006 U.S. Dist. Lexis 19507, at *11 (W.D. Tenn. Mar. 31, 2006) (section 337 preempted claim that drug was sold without FDA-approval, because courts "cannot usurp the FDA's power to evaluate the effectiveness of a drug or to approve a drug"); *Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) (courts "have refused to allow plaintiffs to state a claim based on implicit representations of FDA approval"); *Anthony v. Country Life Mfg., L.L.C.*, 2002 U.S. Dist. Lexis 19445, at *8-9 (N.D. Ill. Oct. 7, 2002) (claim "premised solely upon a (Cont'd)

contrast, plaintiffs' claims in this case do not require referring to, or applying the FDCA. Plaintiffs' claims are based on violation of the Sherman Law and can be resolved with reference to state law alone." Pet. App. at 33. Thus, the district court cases cited by the Grocery Stores are inapposite.

(Cont'd)
violation of the FDCA—that defendant sold nutrition bars containing ingredients that the FDA had not approved"); *Healthpoint, Ltd. v. Ethex Corp.* 273 F. Supp. 2d 817, 838 (W.D. Tex. 2001) ("a party may not use the FDCA to establish a crucial element of a Lanham Act claim"); *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 1997 U.S. Dist. Lexis 2372, at *21 (D. Kan. Feb. 26, 1997) ("even if it were determined in litigation that Calphron did not meet some independent, lay understanding of the term 'dietary supplement', defendants might not be able to remove the term from its label without violating the FDCA"); *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996) (barring claim that defendant "has failed to disclose the fact of FDA non-approval, when the FDA has not yet determined whether or not the product in question has been approved"); *Animal Legal Defense Fund, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 286 (D. Mass. 1986) (plaintiff's claim was preempted because "states cannot impose different or additional affirmative requirements on meat and meat food products"); *National Women's Health Network, Inc. v. A.H. Robins Co.*, 545 F. Supp. 1177, 1180-81 (D. Mass. 1982)

> "No court has ever ordered a notification and recall campaign on the basis of state law. The vast majority of the state law cases cited by plaintiffs are ordinary duty to warn damage actions, a line of cases which is well established but not authority for the much broader form of relief sought in this case."

CONCLUSION

The petition for a writ of certiorari should be denied.

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In The Supreme Court of the United States

ALBERTSON'S, INC., *et al.*,

Petitioners,

v.

JENNIFER KANTER, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The California Supreme Court

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INTRODUCTION

The question presented is not whether traditional state-law causes of action that seek to vindicate independent, distinctive state-law interests are preempted. It is whether private litigation that seeks only to enforce state laws that duplicate federal standards are preempted, when Congress has broadly proscribed private enforcement of the federal standards themselves. The United States never explains why private litigation, which Congress considered to be a direct obstacle to the accomplishment of the Federal Food, Drug, and Cosmetic Act's ("FDCA") purposes when undertaken in federal court, suddenly harmonizes with those statutory purposes when undertaken under identical state law in state courts. The United States reaches its mistaken position not by focusing on the practical impact of private class-action litigation – as implied preemption should – but by focusing on the wrong source of preemption, and by understating the incompatibility of private litigation with the FDCA's federally centralized enforcement scheme.

I. THIS CASE CONCERNS IMPLIED PREEMPTION UNDER FDCA SECTION 337, NOT EXPRESS PREEMPTION UNDER SECTION 343-1.

The United States' recommendation against certiorari rests centrally on its analysis of the "preemptive intent" of FDCA section 343-1, concluding that section 343-1 "does not prevent States from

providing private actions to enforce state requirements that mirror FDCA requirements." (Brief for the United States ("U.S. Br."), pp. 8, 10.) But the question presented by the Petition for Writ of Certiorari ("Petition") is *not* whether section 343-1 of the Nutrition Labeling and Education Act of 1990 ("NLEA") preempts Respondents' claims, but rather whether section 337, enacted more than 50 years earlier, preempts them. It is section 337 – the FDCA's mandate of exclusive government enforcement – that conflicts with private claims seeking to enforce FDCA requirements via state law – not section 343-1.

For that reason, this Court's interpretation of express preemption provisions similar to section 343-1 in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), and *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (U.S. Br., p. 10), has little relevance here. Those decisions, which addressed only whether the challenged state law claims fell within the scope of express preemption provisions akin to section 343-1, never considered section 337 or conflict preemption. (Reply to Brief in Opposition ("Reply"), pp. 8-10.) Although the United States suggests that *Lohr* and *Riegel* "implicitly recogniz[e] that the FDCA does not contain any generally applicable provision preempting [private] suits" (U.S. Br., p. 15), it is axiomatic that cases are not authority for propositions never

considered by the Court, *see, e.g.*, *Waters v. Churchill*, 511 U.S. 661, 678 (1994).[1]

Moreover, the fact that Respondents' state law claims are identical to "FDCA requirements," as section 343-1 requires, does not, as the United States suggests, immunize those claims from "a conflict with the FDCA or its enforcement scheme." (U.S. Br., p. 17.) This Court has repeatedly held that "Congress' inclusion of an express pre-emption clause 'does not bar the ordinary working of conflict pre-emption principles,' that find implied pre-emption" where, as here, "'state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) (quoting *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000) and *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

Wyeth v. Levine, No. 06-1249 (argued Nov. 3, 2008), which also concerns "obstacle" conflict preemption principles in the FDCA context, may shed significant light on the question presented here. Like *Wyeth*, this "is a paradigmatic case of state law frustrating the objectives and purposes of a federal regulatory regime," Petition for Writ of Certiorari, *Wyeth v.*

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[1] In any event, Petitioners have never argued that there is a "generally applicable provision" preempting all private suits. The only suits preempted by section 337 are those that seek to enforce federally prescribed standards.

Levine, 2007 WL 776723, at *25 (Mar. 12, 2007). If the Court does not grant the Petition, Petitioners urge this Court to hold the Petition pending that decision.

II. THE UNITED STATES' CHARACTERIZATION OF CONGRESS' INTENDED ENFORCEMENT SCHEME IS MISGUIDED.

A. Section 337 *Must* Preclude Both Private Federal And Identical State-Law Actions.

In its brief, the United States never explains the question at the heart of this case: why Congress would expressly prohibit private actions and even unsupervised state government actions to enforce the FDCA, but allow unregulable private actions to enforce state laws *identical* to the FDCA. Permitting private litigants to enforce state laws that admittedly "mirror" FDCA requirements (U.S. Br., p. 13) cannot be squared with Congress' intent that such requirements be enforced by government entities alone and that control over such litigation be federally centralized.

The United States' only answer is that Respondents' claims arise from "an independent state-law duty" (U.S. Br., p. 14 n.2) – not, as in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), "solely from the violation of FDCA requirements," *id.* at 352. Respondents' claims, however, are not based on "independent" state laws, but rather on FDA

regulations and identical California law. (JA 169-72.) The only injury alleged is the failure to comply with federal standards duplicated in state law, and Respondents seek only to punish departure from those standards. Just as in *Buckman*, Respondents are not "relying on traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case." *Buckman*, 531 U.S. at 353.

There is, in sum, no distinct or independent state interest that Respondents' complaint seeks to vindicate beyond enforcing compliance with their vision of federal law. While Respondents certainly could bring any claims they might have that – as in *Lohr* – relied on "traditional state tort law which had *predated* the federal enactments in question," *Buckman*, 531 U.S. at 353 (emphasis added), they cannot avoid the impact of section 337 by bringing claims based on state laws that *postdate* and mirror the federal enactments in question.

Moreover, whereas in *Lohr*, as the United States recognizes, plaintiffs sought "a *traditional* damages remedy" (U.S. Br., pp. 10-11 (citing *Lohr*, 518 U.S. at 495) (emphasis added)), here Respondents seek *punitive* damages for violation of federal requirements that Congress intended to be remedied only by seizure, injunction, and civil and criminal penalties. 21 U.S.C. §§ 332-334. Thus, in the absence of *any* independent state interest, the lower court's decision allows an extreme remedy – one that Congress itself

omitted from its enforcement arsenal – for violation of laws *identical* to the FDCA. Under the lower court's decision, massive punitive damages actions could be brought by private class counsel not charged with representing the public interest, even after the FDA had already determined that a warning letter, injunction, or even non-enforcement is appropriate. The resulting multi-million dollar judgments would inevitably lead to over-deterred production and over-protective, non-uniform labeling – the exact consequences Congress sought to avoid by prohibiting private enforcement.

B. Section 343-1 Did Not Alter Congress' Explicit Mandate Of Exclusive Government Enforcement.

The United States adopts the lower court's theory that Congress in 1990 *silently* changed the law to allow private enforcement of state laws identical to the FDCA – when for the prior 50 years it had unequivocally prohibited private enforcement of the FDCA itself. That position inexplicably assumes that in the NLEA, Congress spoke only about state government enforcement, 21 U.S.C. § 337(b), which it went to great lengths to regulate, but actually intended to allow unregulable private enforcement as well, without ever mentioning the subject.

The United States' argument rests on a series of errors. First, it insists that the two pre-NLEA decisions cited in the Petition barring state-law claims to

enforce FDCA requirements "did not cite Section 337 in support of their preemption holdings." (U.S. Br., pp. 15-16.) Not so. *National Women's Health Network, Inc. v. A.H. Robins Co.*, 545 F. Supp. 1177 (D. Mass. 1982), analyzes the language, context, and history of section 337 in detail, and concludes that "[a] private right of action is equally inconsistent with the federal regulatory scheme, whether the right is based in federal or state law." *Id.* at 1179, 1181. *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass.), *aff'd*, 802 F.2d 440 (1st Cir. 1986), quotes *National Women's Health*'s discussion of the "federal regulatory scheme," and – although it does not refer to section 337 by name – quite clearly discusses the provision's preemptive effect: "Massachusetts cannot confer on private persons the power to enforce a federal statute whose enforcement Congress left to federal administrative agencies." *Id.* Thus, contrary to what the United States argues, there *was* uniform case-law interpreting section 337 to preclude state-law FDCA enforcement claims before the NLEA was adopted.[2]

Next, the United States contends that "Petitioners concede that Section 343-1 authorizes States to

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[2] While the United States notes that Congress "presumably was aware that the vast majority of States permitted private parties to enforce state laws prohibiting deceptive business practices" (U.S. Br., p. 10), there is *no* pre-1990 authority – and the United States cites none – permitting private parties to enforce state laws *identical* to the FDCA.

sue to enforce [ ] state requirements and that *Section 337 does not preempt or otherwise limit those suits.*" (U.S. Br., p. 16 (citing Pet. 20) (emphasis added).) Nothing in the Petition – or any of Petitioners' other briefs – makes such a "concession."

But even if Petitioners *had* posited that state governments could enforce FDCA requirements in state court unimpeded by section 337(b), that still would not be "fatal" to Petitioners' preemption argument (U.S. Br., p. 16), because the issue is whether there may be *private* enforcement. In that regard, the FDA itself has underscored the importance of "work[ing] with the States to attempt to ensure that State provisions that are identical to provisions in the act are interpreted by the States in a way that is as consistent as possible with the FDA's interpretation of the Federal provisions." 58 Fed. Reg. 2457-01, 2457-58 (1993). Indeed, the FDA "believes that close cooperation between FDA and the States will ensure that goals of uniformity are met," and to that end has instituted a state training program to guarantee consistency. *Id.* at 2460.

Significantly, in this lengthy discussion of coordinated enforcement between federal and state governments, the FDA never hints at the possibility of private actions. And for good reason. While the FDA can oversee, train, and coordinate with state governments, it cannot possibly work with, supervise, or influence countless plaintiffs' lawyers across the country to ensure that their class actions are "as

consistent as possible with the FDA's interpretation of Federal provisions." 58 Fed. Reg. at 2458.

III. BECAUSE THE IMPACT OF THE CALIFORNIA SUPREME COURT'S DECISION WILL BE IMMEDIATE, REVIEW IS NECESSARY NOW.

The United States argues that review is not necessary now because there are no other federal appellate or state supreme court decisions addressing the preemption of private state-law claims to enforce FDCA requirements, and because the California Supreme Court's decision is interlocutory. This issue, however, cannot wait.

A. The Harmful Impact Of The Decision Is Imminent And Largely Irreparable.

If the California Supreme Court's decision stands, it will have an immediate and profound impact on what had been centralized FDA enforcement. The mere threat of massive damages actions will force businesses that the FDA regulates to undertake widely divergent, over-protective labeling measures that the FDA will have difficulty policing or altering after the fact. The FDA, after all, assuming it learns of such cases and has the resources to participate in them, cannot even appear as of right in state court – further complicating its ability to maintain uniform interpretations of the FDCA and its own regulations. Costly class actions will also significantly

deter industry dialogue with the FDA, elevate food prices that already stand at record highs, and in some instances deter production altogether because of the near impossibility of complying with the labeling demands of private litigants in all 50 states.

The United States poses a straightforward example in which a federal consent decree governing enforcement of a federal labeling requirement preempts a state-law action to enforce an identical state requirement. (U.S. Br., p. 18.) But what if the state-law action – or, more likely, a dozen state-law actions – precede the FDA lawsuit? Those state actions would be brought by various class action counsel who are not obligated to represent the public interest, have no expertise in the FDCA, and have no ability to pursue a unitary enforcement policy. Contrary to what the United States insists, those state-law actions *would* "'skew' the 'delicate balance of statutory objectives' that FDA was charged with achieving." (*Id.*, p. 19 (citing *Buckman*, 531 U.S. at 348).)

It is no answer to say that litigation seeking to impose inconsistent labeling requirements can be expressly preempted. First, that point has no bearing on litigation brought before the FDA formally promulgates a standard in novel areas of application. Second, because the threat of damages is so exponentially high in the class action context, food and drug companies will be forced to settle cases even when their liability exposure is minimal. As Judge Posner observed in *In the Matter of Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293 (7th Cir. 1995), the "sheer

magnitude of the risk to which the class action" exposes defendants puts them under "intense pressure to settle," even where there is a "demonstrated great likelihood that the plaintiffs' claims . . . lack legal merit." *Id.* at 1297-99; *see also, e.g.*, *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1967 (2007) (explaining in class action case that "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases before reaching [summary judgment] proceedings").

Because the effects on industry conduct and ultimately consumers will be so sudden and severe, this Court should not wait for a case that meets the United States' desired level of conflict before granting review.[3] In fact, the only reason why a sharper conflict has not yet materialized is that it had been so clear – until now – that private actions to enforce the FDCA, whether brought under the mantle of federal or state law, are prohibited by section 337. (*See* Petition, pp. 15-16 (citing cases).) The lower court's decision upset that settled law and, if it remains, class action litigation concerning alleged violations of state statutes identical to the FDCA will explode nationwide, far exceeding the FDA's ability to

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[3] While there are no federal appellate or state supreme court cases involving state-law claims to enforce the FDCA, the lower court's decision still cannot be reconciled with *Buckman's* statement that "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with [FDCA] provisions." *Buckman*, 531 U.S. at 349 n.4.

superintend enforcement and wrecking an enforcement regime that has remained intact for the last 70 years.[4]

B. This Court Should Accept Jurisdiction Because The Issue Has Been Finally Decided In State Court And Would Seriously Erode Federal Policy Absent Review.

In a final argument, the United States insists that this Court should deny the Petition because the decision below is interlocutory. (U.S. Br., p. 20.) But this Court has long reviewed state court judgments where, as here,

> the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court, and where reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state court proceedings still to come.

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[4] Even the United States does not dispute that the lower court's decision is likely to be followed in other states, which have unfair competition laws – like California's – that serve as ready vehicles for the private enforcement of FDCA requirements.

Cox Broadcasting Corp. v. Cohn, 420 U.S. 469, 482-83 (1975). In those circumstances, this Court has "entertained and decided the federal issue . . . because *a refusal immediately to review the state court decision might seriously erode federal policy*." *Id.* at 483 (emphasis added); *see also, e.g.*, *Mercantile National Bank v. Langdeau*, 371 U.S. 555, 558 (1963); *Fort Wayne Books, Inc. v. Indiana*, 489 U.S. 46, 47 (1989).

As discussed, permitting private parties to enforce state laws identical to the FDCA would frustrate Congress' intent to keep enforcement in the hands of experienced government entities capable of coordinating their enforcement efforts – thus seriously eroding a 70-year-old federal policy of exclusive government enforcement.

Indeed, in *Buckman*, the Third Circuit – like the California Supreme Court here – reversed the trial court's decision granting defendant's motion to dismiss on federal preemption grounds. *Buckman*, 531 U.S. at 347 (citation omitted). Although the Third Circuit's decision was "interlocutory" and further proceedings had been ordered in the trial court, this Court exercised its certiorari jurisdiction to review the important preemption question presented. *See also Lohr*, 518 U.S. at 482-83 (accepting jurisdiction after Eleventh Circuit partly reversed district court's dismissal on federal preemption grounds and remanded for further proceedings).

Ultimately, neither the United States nor Respondents deny that the California Supreme Court

"has decided an important question of federal law that has not been, but should be, settled by this Court." Sup. Ct. R. 10(c). If this Court refuses jurisdiction now, it could be many years before this Court has another opportunity to review this critically important federal preemption issue. During that time, countless private class actions to enforce the FDCA will be litigated, actions that will "seriously erode the federal policy" of government enforcement that Congress deliberately established more than 70 years ago. *Cox*, 420 U.S. at 483.

CONCLUSION

For all the reasons stated in this Supplemental Brief, the Petition, and the Reply, certiorari should be granted. In the alternative, the Petition should be held pending this Court's decision in *Wyeth v. Levine*, No. 06-1249.

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ALBERTSON'S, INC., *et al.*,

Petitioners,

v.

JENNIFER KANTER, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The California Supreme Court

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INTRODUCTION

Respondents' Brief in Opposition is built entirely on the unsupportable idea that Congress deliberately reserved for the government the power to enforce the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), but licensed private parties to enforce state laws *identical* to the FDCA and its implementing regulations via class actions. Respondents' theory pays no heed to the statutory framework that Congress carefully constructed, which places primary enforcement responsibility and oversight in the hands of the federal government – with a narrow, secondary role for state governments – while precluding *any* form of private enforcement. Their Opposition also ignores the inconvenient truth that the FDCA provides no private right of action, so permitting private state law claims to redress FDCA violations would be as destructive to Congress' government enforcement scheme as a private right to enforce the FDCA itself. Respondents, in sum, offer no way around the conflict between their private FDCA enforcement claims and section 337 of the FDCA, which unequivocally states that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337.

In any event, Respondents' defense of the lower court's decision nowhere denies that the California Supreme Court "decided an important question of federal law that has not been, but should be, settled by this Court." Sup. Ct. R. 10(c). Without question, the California Supreme Court has effected a radical

change in the enforcement of a critical federal statute, opening the door for private parties to decide when and how to redress violations of the FDCA via class actions – decisions that until now have been left to government entities as Congress intended. Without this Court's intervention, the public will no longer benefit from the federal government's judgment, expertise, and ability to maintain a uniform national enforcement policy in coordination with state governments. Petitioners thus respectfully request that this Court solicit the Solicitor General's views before deciding whether to grant review.

ARGUMENT

I. RESPONDENTS' OPPOSITION IS BASED ON THE FALSE PREMISE THAT CONGRESS PROHIBITED PRIVATE ACTIONS TO ENFORCE THE FDCA, BUT ALLOWED PRIVATE SUITS TO ENFORCE STATE LAWS *IDENTICAL* TO THE FDCA.

A. Congress' FDCA Enforcement Scheme Bars Private Actions, Whether Grounded In Federal Or State Law.

Respondents' Opposition is founded on the flimsy notion that their claims are not preempted because they "seek only to enforce state law requirements," not the FDCA itself. (Brief in Opposition ("Opp."), p. 9.) As a threshold matter, Respondents' insistence that their claims are based solely on violations of state law is belied by their own class action complaint, which explicitly alleges that Petitioners violated the FDCA and misbranded their salmon in violation of Food and Drug Administration ("FDA") regulations. (JA 163-164.) In fact, Respondents' claims concerning Petitioners' purported FDCA violations constitute the factual predicate for *all* of their causes of action. (JA 169-172.)[1]

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[1] Contrary to what Respondents suggest in their Opposition (Opp., p. 1), the California Court of Appeal *has* rejected the other grounds argued by Petitioners in support of their demurrer before the trial court. On remand from the California Supreme Court, the Court of Appeal in a May 16, 2008 opinion reversed the trial court's judgment of dismissal based on those other grounds.

But even setting aside the fact that the FDCA lies at the heart of Respondents' complaint, the "state law requirements" that Respondents seek to enforce are – by their own admission – "*identical* to FDCA provisions." (Opp., p. 10; *see also* JA 169-172 (Complaint).)[2] Whatever label they place on their claims, the fact remains that Respondents seek to remedy a violation of FDCA requirements and, in order to succeed, will necessarily have to prove that Petitioners violated the FDCA. Indeed, Respondents' whole basis for claiming a right to private enforcement is FDCA section 343-1, which requires that the state laws enacted by state governments be *identical* to federal law. 21 U.S.C. § 343-1.

Respondents' private action to enforce state laws identical to the FDCA would be just as devastating to Congress' carefully planned government enforcement scheme as a private action to enforce the FDCA itself, which even Respondents do not claim exists. Congress always anticipated that the government would control the enforcement of FDCA standards, and with

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[2] Quizzically, Respondents insist that the question before this Court is whether they "may sue under state law based on state labeling requirements" – not, as Petitioners put it, whether they may bring "state law claims to enforce FDCA requirements." (Opp., pp. 9-11.) But because the state laws on which Respondents rely indisputably duplicate federal requirements wholesale (Opp., p. 3), the "state labeling requirements" at issue in this case are identical to FDCA standards. Thus, Respondents' "question presented" argument is nothing more than a shell game.

that framework in mind afforded the FDA a panoply of enforcement options, 21 U.S.C. §§ 332-334, including restitution and disgorgement, *United States v. Universal Management Servs., Inc.*, 191 F.3d 750, 760-62 (6th Cir. 1999); *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 575-79 (D.N.J. 2004). Allowing a private state law action to remedy all violations of FDCA requirements would rob the FDA of the authority to decide among those options, as well as the discretion *not* to prosecute "minor violations of [the FDCA] whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336. Permitting private class actions to redress conduct in violation of the FDCA would also jeopardize the "major advantages" of government enforcement, "including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a unitary enforcement policy." *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995). It would wrest enforcement from the hands of experienced government entities capable of coordinating their enforcement efforts, resulting in inconsistent lawsuits, inconsistent judgments, and inconsistent enforcement.

For those very reasons, lower courts have consistently dismissed state law claims "involv[ing] all the facts and arguments to be determined in a misbranding enforcement action, matters within the sole jurisdiction of the FDA," *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 838 (W.D. Tex. 2001), as

attempts to circumvent the FDCA's express prohibition against private enforcement actions. Petition for a Writ of Certiorari ("Petition"), pp. 15-16 (citing cases). While Respondents confusingly maintain that those cases "'invariably deal with a party seeking to enforce (sometimes through the use of state law) the FDCA,'" and that their claims "do not require referring to, or applying the FDCA" (Opp., pp. 21-22 (quoting Pet. App. 31)), ultimately *all* claims to enforce state laws identical to the FDCA necessitate establishing a violation of federal standards – a responsibility that Congress entrusted to the government, *see, e.g., Heckler v. Chaney,* 470 U.S. 821, 835 (1985) (recognizing that the FDCA's "enforcement provisions . . . commit complete discretion to the [FDA] to decide how and when they should be exercised"); *United States v. Sullivan,* 332 U.S. 689, 694 (1948) (discussing the wide prosecutorial discretion that the FDCA affords the FDA).

Congress' deliberate objective, in sum, was to prohibit *all* private enforcement actions, which – whether based on federal or identical state law – compromise the "major advantages" of exclusive government enforcement. *Bailey v. Johnson,* 48 F.3d at 968. Because the preclusion of private actions to enforce federal standards was Congress' "clear and manifest purpose," any presumption against preemption was overcome when Congress enacted the FDCA in 1938 and barred private enforcement of the

FDCA.[3] *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996) (presumption against preemption does not apply where preemption was Congress' "clear and manifest purpose").

B. Congress Did Not Alter Its Prohibition Against Private Enforcement Actions When It Amended The FDCA In 1990.

Without any statutory analysis, Respondents insist in their Opposition that FDCA section 343-1, part of the 1990 amendments to the FDCA, "permits states to adopt labeling requirements that are identical to federal requirements and to provide private

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[3] Respondents rely on *Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238 (1984) (Opp., p. 12), which addressed whether a state law award was preempted by the Atomic Energy Act, but in that case there was "no indication that Congress even seriously considered precluding the use of [state] remedies when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959." *Id.* at 251. To the contrary, the Act's legislative history signaled that "Congress assumed that such remedies would be available." *Id.* In contrast with the Atomic Energy Act at issue in *Silkwood,* here "we have clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 352 (2001) (citing 21 U.S.C. § 337).

Moreover, while the Atomic Energy Act discussed in *Silkwood* failed to provide any federal remedy to persons injured by nuclear accidents, *Silkwood,* 464 U.S. at 251, the FDCA gives the FDA the authority to obtain restitution and disgorgement on behalf of persons injured by FDCA violations, *Universal Management Servs., Inc.,* 191 F.3d at 760-62; *Lane Labs-USA, Inc.,* 324 F. Supp. 2d at 575-79.

remedies for violation of those requirements." (Opp., p. 17.)

While section 343-1 undoubtedly permits states to adopt labeling requirements identical to federal standards, there is no evidence that Congress intended to "provide private remedies for violation of those requirements" – and Respondents cite none. As explained in the Petition, when Congress amended the FDCA in 1990, it knew that section 337 had been consistently interpreted to preclude private actions brought under both federal and state law. It easily could have declared, while permitting states to enact laws identical to certain FDCA provisions, that it was also opening the door to private state law claims to enforce those federal standards. Instead, Congress in 1990 was silent with respect to private actions, carving out only a narrow, detailed exception to exclusive federal enforcement for state governments. 21 U.S.C. § 337(b). Certainly, Congress would have given some signal before effecting a monumental change to its decades-old regime of government enforcement.[4]

Respondents have no response to those statutory arguments, nor could they. Instead, they rely on three

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[4] Further devastating Respondents' theory is the 1990 amendments' legislative history, which indicates that Congress intended for the state laws enacted pursuant to section 343-1 to be enforced only by "governmental entities." (Pet. App. 74 (H.R. Rep. No. 101-538, 2d Sess., p. 8 (1990).) Respondents present no contrary history in their Opposition.

of this Court's decisions, *Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996), *Bates v. Dow Agrosciences LLC,* 544 U.S. 431 (2005), and *Riegel v. Medtronic, Inc.,* 128 S. Ct. 999 (2008), none of which has any relevance here. All three cases addressed only whether the challenged state law claims fell within the scope of the express preemption provisions at issue there, never addressing the possibility of conflict preemption under section 337.

In *Medtronic* and *Riegel,* this Court analyzed the express preemption provision found in the FDCA's Medical Device Amendments, section 360k, which preempts state laws "different from, or in addition to" federal requirements. 21 U.S.C. § 360k. This Court, however, never considered section 337. *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 352 (2001) ("*Medtronic* did not squarely address the question of implied pre-emption."); *Riegel,* 128 S. Ct. at 1011 (stating that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," without considering section 337). Although Respondents question in their Opposition "why this Court would hold that private remedies for the violation of parallel state laws are not preempted if Congress clearly and manifestly intended to bar such claims by means of § 337" (Opp., p. 17), it is axiomatic that cases are not authority for propositions never considered by the Court, *see, e.g., Waters v. Churchill,* 511 U.S. 661, 678 (1994) ("These cases cannot be read as foreclosing an argument that they never dealt with.").

Similarly, *Bates* was limited to an interpretation of the Federal Insecticide, Fungicide, and Rodenticide Act's ("FIFRA") express preemption provision, section 136v(b), concluding that the provision did not "pre-empt any state rules that are fully consistent with federal requirements." *Bates*, 544 U.S. at 452. This Court expressly refused to consider petitioners' conflict preemption argument, confining its decision to a determination of "the ordinary meaning of § 136v(b)." *Id.* at 458. In any event, because FIFRA has no provision analogous to section 337, there was no possibility in *Bates* that plaintiffs' private state law claims could conflict with FIFRA's enforcement scheme. *Id.* at 448.

In sum, neither *Medtronic*, *Riegel*, nor *Bates*, which were explicitly confined to the express preemption provisions before the Court, supports Respondents' theory that section 343-1 somehow immunizes private state law claims identical to federal requirements from the preemptive effect of section 337. In fact, this Court has expressly held that "Congress' inclusion of an express pre-emption clause 'does not bar the ordinary working of conflict pre-emption principles,' that find implied pre-emption '. . . where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) (quoting *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000) and *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)); *see also Buckman*, 531 U.S. at 352.

C. Respondents' Private State Law Claims To Enforce Federal Requirements *Are* At Odds With *Buckman*, Which Recognized That Private Parties Cannot Sue For Violation Of The FDCA.

Respondents' attempts to shield their claims from *Buckman's* straightforward holding that "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with [FDCA] provisions," *Buckman,* 531 U.S. at 349 n.4, fall flat.

First, Respondents argue that their claims are not preempted under *Buckman* because they – unlike the *Buckman* plaintiffs – "rely on traditional state requirements that predate the FDCA." (Opp., p. 14.) Not so. Respondents' complaint relies on Sherman Law provisions, all of which replicate and post-date the FDCA. (JA 169.)

Second, Respondents mistakenly argue that unlike in *Buckman,* "the existence of the federal requirements regarding the labeling of foods is not an element of [their] case, let alone a critical element." (Opp., p. 15.) Federal standards that have been imported word-for-word into state law, however, are the beginning and end of Respondents' case. The notion that Respondents' claims did not arise "solely from the violation of FDCA requirements" (Opp., p. 15 (quoting *Buckman,* 531 U.S. at 352-53)) is absurd, because their claims are wholly predicated on California Health & Safety Code provisions that duplicate

federal standards exactly. Despite Respondents' efforts to confuse the issue with artful semantics, the bottom line is that the "state law requirements" on which they rely (Opp., p. 9) *are* federal standards.[5]

II. IN DEFENDING THE CALIFORNIA SUPREME COURT'S DECISION ON THE MERITS, RESPONDENTS DO NOT – AND CANNOT – DISPUTE THAT IT DECIDED AN IMPORTANT QUESTION OF FEDERAL LAW WITH FAR-REACHING CONSEQUENCES.

Respondents' Opposition is most significant not for what it says, but for what it does not say. Respondents nowhere deny that the California Supreme Court "has decided an important question of federal law that has not been, but should be, settled by this Court." Sup. Ct. R. 10(c). Nor do they deny that the California Supreme Court's decision will transfer control over FDCA enforcement from the federal and state governments to numerous class action counsel without the requisite expertise or interest in coordinating their efforts with those governments. Respondents also apparently agree that the California

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[5] In *Medtronic*, by contrast, plaintiffs' "claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." *Buckman*, 531 U.S. at 352 (citing *Medtronic*, 518 U.S. at 481). While negligence claims that borrow federal standards involve additional elements of proof, here Respondents' state law claims are predicated on the same facts as an FDCA claim, and their elements are indistinguishable.

Supreme Court's decision is likely to be widely followed in other states.

Perhaps most importantly, Respondents present no reason why this Court should not call for the views of the Solicitor General before deciding whether review is appropriate. As discussed in the Petition, the FDA anticipated "work[ing] with the States to attempt to ensure that State provisions that are identical to provisions in the act are interpreted by the States in a way that is as consistent as possible with the FDA's interpretation of the Federal provisions." 58 Fed. Reg. 2457-01, 2458 (1993). It did not anticipate the impossible task of working with countless class action counsel to attempt to achieve a consistent interpretation and a uniform approach. Petitioners thus urge this Court to obtain the Solicitor General's views before condoning the decision below, which will topple a 70-year-old government enforcement regime.

CONCLUSION

The Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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In the Supreme Court of the United States

ALBERTSON'S, INC., ET AL., PETITIONERS

v.

JENNIFER KANTER, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF CALIFORNIA

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, preempts respondents' suit to enforce state food-labeling requirements that are identical to requirements imposed under the FDCA.

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ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF CALIFORNIA

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, prohibits the misbranding of food in interstate commerce. 21 U.S.C. 331(a)-(c) and (k). A food containing artificial coloring is misbranded "unless it bears labeling stating that fact." 21 U.S.C. 343(k). The Food and Drug Administration (FDA), which has authority to regulate the labeling of food products, has promulgated regulations providing that farmed salmon may be fed certain color additives "to enhance the * * * color of th[eir] flesh," 21 C.F.R. 73.35(c)(1), 73.75(c)(3)(ii), but "[t]he presence of the color additive * * * shall be declared" in the labeling,

21 C.F.R. 73.35(d)(3), 73.75(d)(4). The declaration may be accomplished by identifying the specific color additive or, alternatively, by using "an * * * informative term" such as "'Color Added' * * * that makes clear that a color additive has been used in the food." 21 C.F.R. 101.22(k)(2). See 21 U.S.C. 371(a), 393(b)(2)(A) and (d)(2) (Secretary of Health and Human Services, through FDA, may promulgate regulations to implement, and is otherwise responsible for executing, the FDCA, including its food-labeling requirements).

In 1990, Congress amended the FDCA to include additional requirements relating to food labeling. Nutrition Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2353. The NLEA contains an express preemption provision that generally prohibits States from establishing or continuing in effect "any requirement for the labeling of food" with artificial coloring "that is not identical to the requirement[s]" of 21 U.S.C. 343(k). 21 U.S.C. 343-1(a)(3). The NLEA preemption provision contains specified exceptions, and it authorizes FDA to grant additional exemptions under certain circumstances. 21 U.S.C. 343-1. The NLEA states that its provisions "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [the NLEA]." § 6(c)(1), 104 Stat. 2364.

The FDCA provides that, in general, "proceedings for the enforcement, or to restrain violations, of the [FDCA] shall be by and in the name of the United States." 21 U.S.C. 337(a). Under an amendment added by the NLEA, a State may also bring proceedings, "in its own name and within its jurisdiction," to enforce certain food-labeling provisions of the FDCA if the State complies with specified procedural requirements. 21

U.S.C. 337(b). In particular, before commencing proceedings, a State must notify FDA and provide adequate time for FDA to bring its own enforcement action. 21 U.S.C. 337(b)(2)(A)-(B). A State may not bring its own action to enforce the FDCA if FDA "is diligently prosecuting a proceeding in court" pertaining to the food in question, "has settled such proceeding, or has settled [an] informal or formal enforcement action pertaining to such food." 21 U.S.C. 337(b)(2)(C).

2. As permitted by Section 343-1, California regulates the labeling of food under the Sherman Food, Drug, and Cosmetic Law (Sherman Law), Cal. Health & Safety Code §§ 109875 *et seq.* (West 2006). Like the FDCA, the Sherman Law provides that a food containing artificial coloring is misbranded "unless its labeling states that fact." Compare *id.* § 110740 with 21 U.S.C. 343(k). The Sherman Law's specific labeling requirements directly incorporate regulations promulgated under the FDCA. See Cal. Health & Safety Code §§ 110085, 110090, 110100(a) (West 2006) (providing that current and future federal food-additive, color-additive, and food-labeling regulations shall be the "regulations of [California]"). California's food-labeling requirements are, therefore, substantively identical to the requirements of the FDCA.

3. Respondents, who are consumers of farmed salmon in California, filed a class action against petitioners in state court. Compl. paras. 1-4. Their complaint alleges causes of action for common-law negligent misrepresentation, as well as for violation of California consumer protection laws prohibiting unfair competition, false advertising, and unfair and deceptive trade practices. Compl. paras. 46-64; see Cal. Bus. & Prof. Code §§ 17200 *et seq.* (West 2008) (unfair competition); *id.*

§ 17500 (false advertising); Cal. Civ. Code §§ 1750 *et seq.* (West 1998) (unfair and deceptive trade practices). All four causes of action are based on the claim that petitioners "fail[ed] to label * * * farm-raised salmon as artificially colored * * * in violation of the [FDCA] and equivalent provisions of California law," including the Sherman Law. Compl. para. 28.

In response to a demurrer filed by petitioners, the California state trial court held that 21 U.S.C. 337 preempts respondents' suit. Pet. App. 51-65. Respondents elected not to amend their complaint, and the trial court dismissed the action. *Id.* at 40-41.

The California Court of Appeal affirmed the dismissal. Pet. App. 36-50. The court held that "section 337(a) impliedly preempts all of [respondents'] causes of action." *Id.* at 38. The court stated that, "[i]n section 337(a), Congress clearly expressed its intention to preclude private enforcement of the FDCA." *Id.* at 46. The preclusion of a private right of action under federal law, the court reasoned, reflected an effort to "afford[] the federal government a degree of oversight of the enforcement of the act." *Id.* at 46-47. In the court's view, allowing "a state law private right of action *based on a violation of the FDCA* would interfere with that governmental prosecutorial discretion and * * * conflict with the clear congressional intent to provide for a comprehensive and exclusive governmental enforcement scheme." *Id.* at 47. Accordingly, the court concluded that Section 337(a) impliedly preempts "any private state law cause of action" based on "conduct [that] would [violate] the FDCA." *Id.* at 47-48. The court explained that, if the facts "plaintiffs will necessarily have to prove in order to recover under their state law claims * * * demonstrate violations of the FDCA, then preemption

will apply irrespective of the particular state law theories of recovery relied upon by the plaintiffs." *Id.* at 49-50.

4. The California Supreme Court reversed and remanded for further proceedings. Pet. App. 1-35. The court held that the FDCA does not preempt respondents' suit to enforce state-law food-labeling requirements identical to FDCA requirements. *Id.* at 3.

The court first determined that 21 U.S.C. 343-1 indicates that States may enact and provide for enforcement of food-labeling requirements that are identical to FDCA requirements. Pet. App. 8-9, 17-27. The court reasoned that, "[a]lthough section 343-1 speaks in terms of what states may *not* do, by negative implication, section 343-1 also expresses what states *may* do." *Id.* at 9. In the court's view, "[t]he words of section 343-1 clearly and unmistakably evince Congress's intent to authorize states to establish laws that are 'identical to' federal law." *Id.* at 17 (quoting 21 U.S.C. 343-1(a)(3)).

The court next concluded that "nothing in the text of section 343-1 or its legislative history supports the assertion that Congress intended to limit the scope of remedies states might choose to provide" for violations of parallel state requirements. Pet. App. 27. The court observed that, "[w]hile Congress clearly stated its intent to allow states to establish their own identical laws, it said absolutely nothing about proscribing the range of available remedies states might choose to provide for the violation of those laws." *Id.* at 18. The court noted that Representative Waxman, who introduced the NLEA in the House of Representatives, explained that the state requirements "may be enforced in State court," without suggesting that enforcement would be restricted to actions brought by States themselves. *Ibid.* (quoting

136 Cong. Rec. 20,419 (1990)). The court reasoned that the absence of any suggestion that Congress intended to preclude private enforcement strongly suggests that it did not so intend, because Congress was presumably aware that "virtually every state in the nation permits one or more nongovernmental parties to enforce" state laws prohibiting unfair and deceptive practices. *Id.* at 20 (quoting Bob Cohen, Annotation, *Right to Private Action Under State Consumer Protection Act—Preconditions to Action*, 117 A.L.R.5th 155 (2004)). That conclusion, the court observed, is also supported by Section 6(c)(1) of the NLEA, which indicates that the preemptive effect of the NLEA "sweep[s] no further than the plain language of the statute itself." *Ibid.*

The California Supreme Court found additional support for its conclusion in this Court's decisions in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), and *Bates* v. *Dow Agroscience LLC*, 544 U.S. 431 (2005). Pet. App. 24-26. The court noted that, in those cases, this Court construed preemption provisions that closely resemble Section 343-1 and concluded that those provisions authorized States not only "to adopt identical requirements" but also "to provide for private remedies for violations of those requirements." *Id.* at 25; see *id.* at 26. Accordingly, the state supreme court concluded, "Congress's decision not to expressly supplant private claims based on * * * state laws authorized by section 343-1 should be interpreted as its considered decision to continue to allow states to provide such private remedies." *Id.* at 20.

The court then considered and rejected petitioners' contention that, notwithstanding Section 343-1, respondents' suit is impliedly preempted by 21 U.S.C. 337. The court observed that Section 337, "by its very terms, only

implicates efforts to enforce *federal* law." Pet. App. 29. Respondents, the court explained, "do not seek to enforce the FDCA; rather their deceptive marketing claims are predicated on violations of obligations imposed by the Sherman Law." *Id.* at 28. "That the Sherman Law imposes obligations identical to those imposed by the FDCA, as it must under section 343-1," the court reasoned, "does not substantively transform [respondents'] action into one seeking to enforce the FDCA." *Ibid.*

The court noted that FDA has stated that Section 337 "applies only to proceedings to enforce the [FDCA]" and that therefore "[n]othing in [Section 337] would preclude a State from taking action against a particular food under *its own state law.*" Pet. App. 29 (quoting 58 Fed. Reg. 2458 (1993)) (brackets and italics added by court). Likewise, the court reasoned, Section 337 does not "affect the ability of states to provide a private remedy for violations of their laws if they so choose." *Id.* at 30.

The court also noted petitioners' admission that, notwithstanding Section 337(b), "states may enforce their own laws in state court without notifying FDA at all, even [when] the laws impose requirements identical to those contained in the FDCA." Pet. App. 34. The court observed that petitioners had failed to explain why private enforcement of state laws "would be of any greater concern to Congress than [state] enforcement of state laws," when "in both instances[] state laws identical to the FDCA are enforced without first notifying the FDA." *Ibid.* Accordingly, the court concluded that the FDCA "does not impliedly preempt private actions based on violations of state laws explicitly authorized by section 343-1." *Id.* at 35.

DISCUSSION

The California Supreme Court's ruling that the FDCA does not preempt respondents' state-law suit is correct. The state supreme court's decision does not conflict with any decision of this Court or a federal court of appeals. Moreover, the state supreme court's decision is interlocutory, and further proceedings may clarify the nature of any preemption issue that might be presented. Accordingly, the Court should deny the petition for a writ of certiorari.

A. The Decision Below Is Correct

The California Supreme Court correctly held that the FDCA does not preempt respondents' action to enforce state food-labeling requirements that are identical to requirements imposed under the FDCA. Under 21 U.S.C. 343-1, States are generally permitted to enact and to provide for the enforcement of those state requirements. Although 21 U.S.C. 337 precludes private actions to enforce the FDCA itself, Section 337 does not prohibit private actions to enforce parallel state requirements. A particular state-law suit might, in certain circumstances, impliedly conflict with provisions of the FDCA, implementing regulations, or a particular determination or enforcement action by FDA, but respondents' suit poses no such conflict.

1. Because Section 343-1 expressly addresses preemption of state food-labeling requirements, analysis of the preemption question "must in the first instance focus on the plain wording of [that provision], which necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993). As the California Supreme Court correctly concluded, Section 343-1 indicates that Congress gener-

ally intended to permit States to adopt food-labeling requirements identical to FDCA requirements and to provide for the enforcement of those state requirements in state court. See Pet. App. 17-27.

The plain text of Section 343-1 prohibits States from adopting "any requirement for the labeling of food" with artificial coloring "that is *not* identical to the requirement[s]" of 21 U.S.C. 343(k), the FDCA provision addressing artificial coloring. 21 U.S.C. 343-1(a)(3) (emphasis added). As the California Supreme Court recognized, by preempting only requirements that are "not identical" to federal requirements, Section 343-1 strongly suggests that States *may* adopt requirements that *are* identical to federal requirements. Pet. App. 9, 17. That conclusion is strengthened by Section 6(c)(1) of the NLEA, which indicates that Congress did not intend the preemptive effect of any provision of the NLEA, including Section 343-1, to extend beyond its express language. See 21 U.S.C. 343-1 note.

As the California Supreme Court also correctly concluded, nothing in Section 343-1 suggests that Congress intended to limit the States' authority to prescribe the remedies for violations of the state requirements permitted by Section 343-1. Pet. App. 18-27. "States are independent sovereigns with plenary authority to make and enforce their own laws as long as they do not infringe on federal constitutional guarantees." *Danforth* v. *Minnesota*, 128 S. Ct. 1029, 1041 (2008). Although Congress, under the Supremacy Clause, may displace the remedies States have provided for violations of state law that does not conflict with federal law as a substantive matter, this Court has been hesitant to conclude that Congress intends such "a serious intrusion into state sovereignty." *Medtronic, Inc.* v. *Lohr*, 518 U.S.

470, 488 (1996) (plurality opinion). Moreover, when Congress enacted Section 343-1, it presumably was aware that the vast majority of States permitted private parties to enforce state laws prohibiting deceptive business practices. See Pet. App. 20; Jeff Sovern, *Private Actions Under the Deceptive Trade Practices Acts: Reconsidering the FTC Act As Rule Model*, 52 Ohio St. L.J. 437, 448 (1991); see also U.S. Amicus Br. 3, *Altria Group, Inc.* v. *Good*, No. 07-562 (argued Oct. 6, 2008).[1] Against that backdrop, the absence of any indication that Congress intended to preclude States from authorizing private actions to enforce state substantive requirements that are not themselves preempted strongly suggests that Congress did not foreclose such suits.

The conclusion that Section 343-1 does not prevent States from providing private actions to enforce state requirements that mirror FDCA requirements accords with this Court's interpretation of similar preemption provisions. In *Lohr*, the Court construed 21 U.S.C. 360k, a provision of the FDCA that prohibits States from establishing "any requirement * * * different from, or in addition to," FDCA labeling and design requirements for medical devices. The Court concluded that Section 360k does not preempt "State or local requirements that are equal to, or *substantially identical* to, requirements imposed by or under the [FDCA]." 518 U.S. at 496-497 (emphasis added) (quoting 21 C.F.R. 808.1(d)(2)). All nine Justices also agreed that Section 360k permits States "to provide a traditional damages

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[1] As explained in the United States' amicus brief in *Wyeth* v. *Levine*, No. 06-1249 (argued Nov. 3, 2008), such suits would be preempted where the substantive state law to be applied conflicted with the FDCA, implementing regulations, or an approval or other determination made by FDA.

remedy for violations of" those identical state requirements. *Id.* at 495; see *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The Court recently reiterated that understanding of Section 360k in *Riegel* v. *Medtronic, Inc.*, 128 S. Ct. 999 (2008), observing that Section 360k "does not prevent a State from providing a damages remedy" where "the state duties" being enforced "'parallel,' rather than add to, federal requirements." *Id.* at 1011 (quoting *Lohr*, 518 U.S. at 495).

In *Bates* v. *Dow Agriscience LLC*, 544 U.S. 431 (2005), this Court adopted a similar interpretation of 7 U.S.C. 136v(b), a statutory provision prohibiting States from adopting "any requirements * * * in addition to or different from those required" by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The Court held that, under the plain language of that provision, "a state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Bates*, 544 U.S. at 447. The Court further held that, "although FIFRA does not provide a federal remedy to farmers and others who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements, nothing in § 136v(b) precludes States from providing such a remedy." *Id.* at 448. Consistent with *Lohr* and *Bates*, the California Supreme Court correctly concluded that Section 343-1 indicates that Congress did not intend to preclude States from providing private remedies for violation of state requirements that parallel requirements under the FDCA.

2. Notwithstanding Section 343-1, petitioners contend that Section 337 impliedly preempts respondents' suit. Petitioners assert that Section 337 precludes all private actions requiring proof of facts "that would sup-

port an FDCA claim" (Pet. 16), including suits under state law to enforce the parallel state requirements authorized by Section 343-1. Apparently relying on the principle that state law is impliedly preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941), petitioners contend that private actions to enforce parallel state requirements would interfere with the "exclusive government enforcement scheme" that they assert is embodied in Section 337. Pet. 13. The California Supreme Court correctly rejected petitioners' contentions. See Pet. App. 27-35.

a. Nothing in the text of Section 337 suggests that it precludes actions under state law. Section 337(a) provides that, in general, "proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. 337(a). Section 337(b) authorizes a State to bring an action to enforce specified provisions of the FDCA provided that the State complies with procedural requirements designed to ensure coordination with the FDA. 21 U.S.C. 337(b).

As FDA recognized when it promulgated regulations to implement Section 337(b), Section 337 "applies only to proceedings to enforce the [FDCA]." 58 Fed. Reg. at 2458. Accordingly, FDA concluded that Section 337 "does not prohibit a State from enforcing an identical State law." *Ibid.* Similarly, Section 337 does not prohibit a State from authorizing private suits to enforce such a law. Pet. App. 30.

Actions to enforce state laws that impose requirements identical to those under the FDCA are not actions to enforce the FDCA itself. Petitioners contend that

such state actions always "necessitate establishing a violation of federal standards." Pet. Reply Br. 6; see *id.* at 4. As respondents' suit itself demonstrates, however, that contention is incorrect. Respondents' suit "can be resolved with reference to state law alone." Pet. App. 33. Their claims are predicated on violations of California's Sherman Law, which provides that food is misbranded "if it bears or contains any * * * artificial coloring * * * unless its labeling states that fact." Cal. Health & Safety Code § 110740 (West 2006). Although that requirement mirrors the FDCA's requirement in 21 U.S.C. 343(k), respondents can prove that petitioners violated the Sherman Law requirement without even referring to the FDCA.

Respondents can also prove that petitioners violated the Sherman Law by proving that they violated FDCA regulations, Cal. Health & Safety Code § 110100(a) (West 2006), and respondents' complaint contains such allegations, Compl. para. 28. But, as this Court has explained, even when state-law claims are predicated on violations of the FDCA, they remain state-law claims. In *Lohr*, this Court held that the FDCA did not preempt state-law claims that included allegations that the defendant had "violated FDA regulations." 518 U.S. at 495. In *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court rejected the plaintiffs' "attempt to characterize * * * the claims at issue in [*Lohr*] * * * as 'claims arising from violations of FDCA requirements.'" *Id.* at 352 (citation omitted). As the Court explained, that characterization was inaccurate because the claims in *Lohr* arose from a state-law duty, "not solely from the violation of FDCA requirements." *Ibid.*; see also *Merrell Dow Pharm. Inc.* v. *Thompson*, 478 U.S. 804, 808, 809, 813 (1986). The same

is true of respondents' claims here.[2] "[T]he party who brings a suit is master to decide what law he will rely upon," *Fair* v. *Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1913) (Holmes, J.), and may therefore sue only under state law whether or not the same allegations would support a federal-law cause of action. See, *e.g.*, *Merrell Dow*, 478 U.S. at 809 & n.6.

b. This Court's decisions in *Lohr* and *Riegel* strongly support the conclusion that Section 337 does not prohibit private suits to enforce state laws that parallel the requirements of the FDCA. In *Lohr*, after concluding that Section 360k does not preempt tort actions under state law if they "rest on claims that [the defendant] negligently failed to comply with duties 'equal to, or substantially identical to, requirements imposed' under [the FDCA]," the Court held that "there was no reason for

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[2] As explained above, California law imposes an independent state-law duty that requires the labeling of food that contains artificial coloring to state that fact. See Cal. Health & Safety Code § 110740 (West 2006). Moreover, respondents' claims, like the state-law tort claims in *Lohr*, require proof not only of violation of that state requirement but also of additional elements, such as damage or injury as a result of the violation. See Cal. Civ. Code § 1780 (West Supp. 2008) (requiring proof that damage resulted from the unfair or deceptive practice); Cal. Bus. & Prof. Code §§ 17204, 17535 (West 2008) (requiring proof of injury in fact and loss of money or property as a result of unfair competition or false advertising); *Apollo Capital Fund, LLC* v. *Roth Capital Partners, LLC*, 70 Cal. Rptr. 3d 199, 213 (Cal. App. 2007) (stating that proof of justifiable reliance and resulting damage is necessary to establish negligent misrepresentation). The existence of those additional elements reinforces the conclusion that respondents are not seeking to enforce the FDCA itself but rather to enforce a parallel state-law duty that the FDCA does not preempt. See also *Lohr*, 518 U.S. at 495 (explaining that the fact that plaintiffs must prove additional elements to prevail on their state-law claims does not make the state-law requirements "different from" federal requirements for preemption purposes).

the Court of Appeals to preclude" such claims. 518 U.S. at 497. The dissenting Justices agreed with that aspect of the Court's holding. See *id.* at 513 (opinion of O'Connor, J.). No Member of the Court suggested that parallel state-law claims might be precluded by Section 337. And if Section 337 imposed a blanket prohibition on such claims, the Court's holding that the claims in *Lohr* could proceed could not be sustained. Similarly, in *Riegel*, the Court concluded that state requirements for medical devices are preempted "only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law," implicitly recognizing that the FDCA does not contain any generally applicable provision preempting such suits. 128 S. Ct. at 1011 (quoting 21 U.S.C. 360k(a)).

c. Petitioners nonetheless contend that Section 337 broadly preempts all private actions to enforce state laws that parallel FDCA requirements because, according to petitioners, courts had uniformly construed Section 337 to preempt such suits before Congress enacted the NLEA, and nothing in the NLEA changed the state of the law. Pet. 13-14, 17-21. Petitioners are wrong on both counts.

First, no uniform line of authority had interpreted Section 337 to preclude state-law causes of action before enactment of the NLEA. Petitioners cite only one court of appeals decision and two district court cases in support of their contention. The court of appeals decision did not address state-law claims. It held only that the FDCA does not itself provide a private right of action. *Pacific Trading Co.* v. *Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976). The two district court decisions held that state-law actions were preempted, but the decisions did not cite Section 337 in support of their preemption

holdings. See *Animal Legal Def. Fund Boston, Inc.* v. *Provimi Veal Corp.*, 626 F. Supp. 278, 283-284 (D. Mass.), aff'd, 802 F.2d 440 (1st Cir. 1986) (*Animal Legal Defense Fund*); *National Women's Health Network, Inc.* v. *A.H. Robins Co.*, 545 F. Supp. 1177, 1180-1181 (D. Mass. 1982) (*National Women's Health*). The courts relied primarily on what they described as the "comprehensive" or "pervasive" nature of the particular regulatory schemes—the regulations concerning medicated animal feeds and new animal drugs in *Animal Legal Defense Fund*, see 626 F. Supp. at 283-284, and the regulations concerning medical devices in *National Women's Health*, see 545 F. Supp. at 1181. In any event, as explained above, this Court has since concluded in both *Lohr* and *Riegel* that private suits can be brought based on violations of state law that parallel federal requirements.

Second, Section 343-1, which was enacted as part of the NLEA, signaled Congress's intent to permit States to adopt food-labeling requirements identical to FDCA requirements and to provide for the enforcement of those state requirements in state court. See pp. 8-11, *supra*. Indeed, petitioners concede that Section 343-1 authorizes States to sue to enforce such state requirements and that Section 337 does not preempt or otherwise limit those suits. Pet. 20. As the California Supreme Court recognized, that concession is fatal to petitioners' contention that Section 337 nonetheless preempts States from authorizing private suits to enforce the same state requirements. See Pet. App. 33-34. If Section 337(b)'s restrictions on a State's direct enforcement of the FDCA itself do not preempt or otherwise restrict a State's enforcement of its own parallel state requirements, then it follows that Section 337(a)'s re-

strictions on private enforcement of the FDCA likewise do not preempt a State from allowing private suits based on those parallel state requirements.

d. Petitioners contend that private actions to enforce parallel state requirements would frustrate the FDCA's goal of uniformity in regulation and enforcement. Pet. 21-27; Pet. Reply Br. 5. The interest in uniformity of regulation and enforcement under the FDCA is, however, not so "unyielding" as to bar all private state-law suits concerning food labeling. *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 70 (2002). As described above, Section 343-1 expressly allows States to impose food-labeling requirements that are identical to federal law. Section 343-1 also allows States to impose food-labeling requirements that are not identical to FDCA requirements in specified circumstances or when FDA grants an exemption from preemption. 21 U.S.C. 343-1(a)(1)-(5) and (b). And Section 337(b) even expressly allows States to bring actions to enforce the *federal* FDCA food-labeling requirements themselves. 21 U.S.C. 337(b). Thus, the interest in uniformity does not deprive the States of any role in enforcing food-labeling requirements.

In the view of FDA, private suits under state law to enforce state food-labeling requirements that parallel FDCA requirements do not necessarily pose a conflict with the FDCA or its enforcement scheme. On the contrary, the requirements of 21 U.S.C. 343-1 will ensure that any state-law action is consistent with federal requirements. Unless the state requirement is "identical" to the federal requirement, or the statute or FDA grants an exemption, the state-law suit will be preempted.

Even a suit to enforce an identical state requirement would be preempted if the particular suit "actually

conflict[ed]" with provisions of the FDCA, implementing regulations, or an administrative determination or enforcement action by FDA. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 874 (2000). For example, FDA might resolve an enforcement action against a food company that had violated the FDCA's labeling requirements by entering into a consent decree under which the company agreed to change its labeling in a particular manner prospectively. FDA might decide, however, that the decree should affirmatively allow products already distributed to remain on the market because they did not present a health or safety risk, they provided recognized nutritional benefit, and the risk from their misbranding was negligible. Once the consent decree was approved by the court, a state-law action against the company to remedy the violation of an identical state labeling requirement might well be preempted, if it would actually conflict with the federal enforcement balance reflected in the consent decree.

Respondents' suit, however, does not pose any such conflict, and the California Supreme Court correctly held that it is not preempted. See *Lohr*, 518 U.S. at 496 ("Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' *Hines*[, 312 U.S. at 67,] and, therefore, whether it should be preempted.") (footnote omitted).

B. The Decision Below Does Not Conflict With Any Decision Of This Court Or A Federal Court Of Appeals

1. Contrary to petitioners' contention (Pet. 12-13, 14-15; Pet. Reply Br. 11-12), the California Supreme Court's decision does not conflict with this Court's decision in *Buckman*. In *Buckman*, the Court held that the FDCA preempted state-law claims alleging that the defendant had made fraudulent representations to FDA in order to secure clearance to market certain medical devices. 531 U.S. at 343-344. The Court concluded that those claims conflicted with federal law because they would "skew[]" the "delicate balance of statutory objectives" that FDA was charged with achieving in policing fraud and administering the device clearance process. *Id.* at 348. The Court explained that, among other things, the claims might deter would-be applicants from seeking approval for beneficial devices or lead applicants to deluge FDA with information that the agency neither wanted nor needed to determine whether to approve the devices. *Id.* at 350-351. Unlike the suit in *Buckman*, respondents' suit does not involve alleged fraud on the FDA, the FDA's approval of a product, or any other FDA determination. Respondents' suit therefore does not pose the concerns about skewing the FDA's approval process on which this Court relied in *Buckman*.

As petitioners note (Pet. 14), in a footnote in *Buckman*, the Court stated in passing that the FDCA does not authorize private litigants to sue for noncompliance with the FDCA's medical device provisions. See 531 U.S. at 349 n.4 (citing 21 U.S.C. 337(a)). But, as explained above, respondents' suit is based on a violation of state law, not the FDCA itself.

2. The decision below also does not conflict with the decision of any federal court of appeals. Petitioners cite three court of appeals decisions and imply that those decisions conflict with the California Supreme Court's decision here. See Pet. 14-15 n.2. All three of those decisions stated that the *FDCA* does not create a *federal* private right of action. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781 (3d Cir. 1999); *PDK Labs, Inc.* v. *Friedlander*, 103 F.3d 1105 (2d Cir. 1997); and *Bailey* v. *Johnson*, 48 F.3d 965 (6th Cir. 1995). None of the decisions, however, addressed the distinct question at issue here—whether the FDCA preempts private actions under *state law* to enforce state requirements that are identical to federal requirements. The court of appeals decisions therefore do not conflict with the holding in this case.

C. The Decision Below Is Interlocutory

Even if the question presented otherwise warranted review, this Court should deny the petition for a writ of certiorari because the decision below is interlocutory. The California Supreme Court merely reversed the dismissal of respondents' complaint and remanded for further proceedings. The state courts therefore have not yet made any determinations concerning whether the elements of respondents' various state-law causes of action are satisfied, the nature of petitioners' conduct, or what form of relief, if any, might be available as a matter of state law. The proceedings on remand will yield more information about the precise contours of respondents' claims and may clarify the nature of any preemption issue that might be presented. Accordingly, it would be premature for the Court to grant review at this time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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IN THE

Supreme Court of the United States

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Petitioners,

v.

JENNIFER KANTER, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the Supreme Court of California

BRIEF AMICI CURIAE OF THE FOOD MARKETING INSTITUTE, THE GROCERY MANUFACTURERS ASSOCIATION, THE INTERNATIONAL DAIRY FOODS ASSOCIATION, AND THE AMERICAN FROZEN FOOD INSTITUTE IN SUPPORT OF PETITIONERS

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Respondents.

On Petition for a Writ of Certiorari to the Supreme Court of California

BRIEF AMICI CURIAE OF THE FOOD MARKETING INSTITUTE, THE GROCERY MANUFACTURERS ASSOCIATION, THE INTERNATIONAL DAIRY FOODS ASSOCIATION, AND THE AMERICAN FROZEN FOOD INSTITUTE IN SUPPORT OF PETITIONERS

STATEMENT OF INTEREST OF AMICI CURIAE

Amicus curiae the Food Marketing Institute ("FMI") is a nonprofit association that represents food retailers and wholesalers in the United States and around the world.[1] FMI's 1,500 member compa-

[1] Pursuant to Sup. Ct. R. 37.2(a), amici curiae note that counsel of record for all parties received notice of amici's intention to file this brief at least 10 days prior to the due date of the brief. Pursuant to Sup. Ct. R. 37.6, amici note that no part of this brief was authored by counsel for any party. Amici also note that no party or counsel made a monetary contribu-

nies run the gamut from large chains to independent markets. Together they operate some 26,000 retail food stores in the United States with a combined annual sales volume of $680 billion—three-quarters of all the retail food store sales in the Nation. FMI counts among its primary goals the promotion of food safety through research and education. Towards that end, FMI helps retailers train employees how to safely handle and prepare food and teaches consumers effective food safety measures. FMI also works with both federal and state governments to help notify the industry of product recalls and foodborne illness outbreaks.

Amicus curiae the Grocery Manufacturers Association ("GMA") is the world's largest association of food, beverage, and consumer product companies. With U.S. sales of more than $460 billion, GMA members employ more than 2.5 million workers in all 50 states. GMA leads efforts to increase productivity and growth in the industry and works to help protect the safety and security of the food supply through scientific excellence.

Amicus curiae the International Dairy Foods Association ("IDFA") represents the nation's $90 billion dairy industry. IDFA's 570 member companies include dairy processors and marketers, cheese and ice cream makers, and their suppliers. The organization's 220 dairy processing members represent more than 85 percent of the milk, cultured products,

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tion intended to fund the preparation or submission of this brief, and that no person or entity other than amici or their members made such a monetary contribution. This brief is filed with the consent of all the parties.

cheese, and frozen desserts produced and marketed in the United States.

Amicus curiae the American Frozen Food Institute ("AFFI") is a national trade association that has promoted and represented the interests of all segments of the frozen food industry, including frozen food manufacturers, processors, marketers, and suppliers, for more than 50 years. AFFI's 550 member companies are responsible for manufacturing, processing, transportation, distribution, and sale of approximately 90 percent of the frozen food produced in the United States, with an annual sales volume exceeding $60 billion. AFFI fosters industry development and growth, advocates on behalf of the industry before legislative and regulatory entities, and provides additional value-added services for its members and for the benefit of consumers.

Amici—who together represent the lion's share of this country's food processing and marketing industry—are united in their grave concern about the decision of the California Supreme Court in this case. For 70 years, Congress has entrusted enforcement of the food labeling rules of the Federal Food, Drug, and Cosmetic Act ("FDCA") to federal—and, to a lesser extent, state—government regulators. This system has functioned smoothly, allowing the Food and Drug Administration ("FDA") to exercise the wisdom of the repeat player. FDA knows which high priority regulatory concerns to target for strict enforcement actions, which deserve only warnings or no action at all, and which require a wait-and-see approach due to still developing scientific or empirical evidence. The agency, in short, can and does exercise the discretion bestowed by Congress to allow

the agency and the food industry to focus on important safety issues.

The California Supreme Court's decision throws that sensible regulatory scheme out the window. The court interpreted a 1990 FDCA amendment intended to largely preempt state regulation to fundamentally invert the statute's structure, allowing private citizens to bring suits (and class actions) to enforce FDCA rules after seven decades during which such private enforcement was considered impermissible. According to the court below, Congress enacted this monumental change to U.S. food law without so much as mentioning that it was doing so in the statute itself or in the legislative history.

As petitioners correctly argue, this conclusion is wrong on the law. But it also is devastating in its practical effects: If allowed to stand, the decision below will open the door to costly class action abuses, drive up already spiraling food prices, and undermine, not enhance, the food industry's and FDA's food safety initiatives. This Court should grant certiorari and reverse the California Supreme Court's ruling on this exceptionally important question.

SUMMARY OF ARGUMENT

The California Supreme Court's erroneous interpretation of the FDCA has real potential to unnecessarily drive up the food industry's legal costs and thus to lighten the wallet of every American. The court's holding permits private citizens to file suit against food companies under "little FDCA" statutes—state food laws with terms identical to those of the federal FDCA. Since most, if not all, states have

enacted little FDCAs, and most, if not all, states have unfair competition laws that would authorize private suits based on violation of the little FDCAs, the rule articulated below will permit unfettered private enforcement of a number of FDCA requirements in every jurisdiction that adopts the California Supreme Court's view.

This change in the long-established status quo would be disastrous. Decades of experience with the class action plaintiffs' bar make it easy to predict that if such FDCA-based causes of action are recognized, lawsuits—and particularly class actions—will multiply. Because the FDCA is a strict liability statute, and because it and its associated regulations contain literally thousands of sometimes complex requirements, food companies could face the risk of huge class action damage claims for minor FDCA violations that, under FDA's current enforcement regime, would lead to nothing more than a warning letter and a quick correction. That increase in litigation, in turn, will drain millions of dollars from these companies' coffers, limiting the resources they have to devote to food safety initiatives and driving up food prices that already stand at record highs.

Such an outcome would not improve food safety, would not help consumers, and indeed would do no one any good, with the possible exception of the class action bar. That, no doubt, is why Congress expressly rejected private enforcement of the FDCA when it crafted the statute. The court below was wrong to obliterate Congress's wise choice on the basis of a statutory amendment that did not so much as hint at a congressional desire to change course.

REASONS FOR GRANTING THE WRIT

I. THE HOLDING BELOW WOULD AUTHORIZE A BROAD RANGE OF FDCA-BASED PRIVATE ACTIONS IN MOST IF NOT ALL STATES.

The FDCA, as amended by the Nutrition Labeling and Education Act of 1990 ("NLEA"), vests enforcement power in the hands of federal and, to a lesser extent, state authorities. *See* 21 U.S.C. §§ 336, 337. As part of its narrow grant of enforcement authority to state regulators, the statute permits states to "establish" or "continue in effect" certain requirements regarding food standards and labeling, but only if the state requirements are "identical" to the requirements of the FDCA itself; any non-identical requirements are forbidden. *Id.* § 343-1(a)(1), (3). Section 343-1 is, on its face, a preemption provision intended to eliminate non-conforming state regulation and hence promote national uniformity. *See* House Debate on H.R. No. 3562, 101st Cong., 2d Sess., 136 Cong. Rec. 5840 (daily ed. July 30, 1990) (remarks of Rep. Waxman). The California Supreme Court, however, read the provision to have a much more dramatic effect than the plain language suggests. It held that, notwithstanding Congress's expressed intent to eschew a private right to enforce the FDCA, Section 343-1 "permits private claims" based on *identical* state laws. Pet. App. 24.

To be sure, this holding comes in a case involving only the FDCA's artificial coloring rules and their California analogues, but the court's logic is not so limited. It is potentially national in scope, and it would permit private actions based not just on the artificial coloring rules but on violations of various

other FDCA regulations as well. That is so for two reasons. First, all or nearly all states have followed California and adopted "little FDCAs" effectively incorporating the FDCA's provisions into state law. And second, Section 343-1—the provision the court below interpreted as permitting private actions based on "identical" state laws—authorizes such state analogues across a significant range of FDCA rules.

A. Most Or All States Have Adopted "Little FDCAs."

California is far from the only state that has adopted a "little FDCA" effectively incorporating the FDCA's rules into state law. On the contrary, it appears that all, or almost all, states have done the same. Amici surveyed 15 state codes for purposes of this brief and found that all 15 have such statutes. Indeed, all 15 have verbatim or near-verbatim versions of 21 U.S.C. § 343(k), the FDCA provision that imposes labeling rules for artificial coloring and that provides the basis for respondents' claims. *See, e.g.*, Alaska Stat. § 17.20.040(a)(11) ("Food is misbranded if * * * it bears or contains artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact"); Ariz. Rev. Stat. § 36-906 (same); Ark. Code Ann. § 20-56-209 (same).[2] As petitioners rightly observe, these state law analogues all can be characterized as consumer protec-

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[2] *See also* Ala. Code 1975 § 2-17-1; Colo. Rev. Stat. § 25-5-411; Conn. Gen. Stat. § 21a-102; Del. Code Ann. Tit. 3, § 8705; Fla. Stat. § 500.11; Ga. Code Ann. § 26-2-28; Haw. Rev. Stat. § 328-10; Idaho Code Ann. § 37-123; 410 Ill. Comp. Stat. 620/11; Ind. Code § 16-42-2-3; Iowa Code § 189A.2; Kan. Stat. Ann. § 65-665.

tion statutes, and violation of a consumer protection statute "automatically constitutes a violation of the unfair competition laws of numerous states." Pet. 23 & n.5. The California Supreme Court's decision thus has the potential to spur the filing of FDCA-based private actions and class actions in every state (or almost every state) in the Nation.

B. The California Supreme Court's Logic Implicates Not Just Labeling But Food Regulations of Various Kinds.

The decision below also has implications beyond the FDCA's artificial coloring rules. Section 343-1, the provision on which the California Supreme Court based its holding, authorizes "identical" state laws not just in the area at issue in this case but also with regard to "standard[s] of identity," 21 U.S.C. § 343-1(a)(1), nutrition labeling, *id.* § 343-1(a)(4), and more. Those categories, in turn, are quite broad. A standard of identity, for example, is a regulation establishing the criteria which must be met before a food may be labeled in a certain way. FDA promulgates countless standards of identity for many different foods, and the logic of the court below suggests that all of those regulations may be enforced *via* private rights of action—at least so long as the states have incorporated FDA regulations as their own.

Many states have done just that. Most, for instance, have codified versions of FDA's regulations as well as the Model Food Code, which runs hundreds of pages and incorporates numerous FDA regulations on top of those explicitly listed in the code. *See* FDA, *Real Progress in Food Code Adoptions* at 1 (Nov. 2007) (reporting that 48 of the 50 states have

adopted some version of the code);[3] FDA, *et al.*, *The Food Code* at 74 (U.S.P.H.S. 2001) (mandating that "Packaged Food shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 * * * and the general requirements in 21 CFR 130 * * * and 9 CFR 319 Subpart A").[4]

Taken together, the near-universal adoption of "little FDCA" statutes, the scope of Section 343-1, and the states' codification of FDA regulations create a legal landscape in which the erroneous decision below may well have a profound effect. In any jurisdiction that follows the California Supreme Court, private plaintiffs arguably would have a cause of action every time a food company commits even a minor violation of one of the many food labeling rules or standards of identity within the ambit of Section 343-1. As amici explain below, such a result would bode ill for both the food industry and American consumers.

II. PRIVATE ENFORCEMENT WOULD IMPOSE ENORMOUS COSTS ON FOOD COMPANIES (AND THUS ON CONSUMERS) WITHOUT ANY CONCOMITANT FOOD SAFETY BENEFIT.

The newly-minted private right of action created by the California Supreme Court would have drastic consequences for the food industry. If experience is any guide, it would not take long for the class action bar to seize on this new opportunity and launch a barrage of lawsuits. Those lawsuits, in turn, likely

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[3] *Available at* http://www.cfsan.fda.gov/~ear/fcadopt.html.

[4] *Available at* http://www.cfsan.fda.gov/~acrobat/fc01.pdf.

would trigger settlement payouts and litigation costs that would hurt the food industry's bottom line, boosting food prices and diverting resources the industry could have used to fund food safety initiatives. And the negative effects would not be limited to the financial sphere. Private lawsuits would target behavior that FDA, with its perspective as an experienced regulator, may have chosen to regard as harmless or even beneficial. And the mere *threat* of lawsuits would make it more difficult for FDA to obtain voluntary industry cooperation when it investigates potential violations.

The real tragedy is that these deleterious effects would not be offset by improvements in food safety. Just the opposite, in fact. FDA has shown that it is quite capable of vigorously enforcing the FDCA. If recognition of private rights of action would have any impact at all, it would be to hinder FDA's enforcement strategy by presenting issues prematurely or in ways that do not reflect the agency's public health priorities. For all of these reasons, the California Supreme Court's holding was not just legally erroneous but also highly unwise.

A. Recognition Of Private Enforcement Rights Inevitably Will Spur The Filing of Class Actions.

There can be little doubt that recognition of private rights of action under the FDCA's state law carbon-copies would lead in short order to an explosion in class action litigation directed at the food industry. *See* Claudia L. Andre, *What's in that Guacamole? How* Bates *and the Power of Preemption Will Affect Litigation Against the Food Industry*, 15 Geo. Mason L. Rev. 227, 248 (Fall 2007) (observing in the context

of tobacco that "[o]nce consumers realized state laws might allow for private causes of action, * * * litigation mushroomed"). That litigation boom, in turn, would mean a drain on food manufacturers' and retailers' coffers, even in cases where the targeted companies did nothing wrong. After all, "[a] * * * common abuse in state court class actions is the use of the class device as 'judicial blackmail' in cases that border on frivolous." S. Rep. No. 109-14, at 20-21 (2005). *See also Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Dabit*, 547 U.S. 71, 81 (2006) (citing legislative findings to the effect that "nuisance filings, targeting of deep-pocket defendants, [and] vexatious discovery requests * * * had become rampant" in the securities class-action context) (quotation omitted).

For amici's smaller member companies in particular, "certification of a class action, even one lacking merit," may "force[ ] these defendants to stake their companies on the outcome of a single jury trial[.] * * * [Defendants] may not wish to roll these dice. That is putting it mildly. They will be under intense pressure to settle." *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1298-99 (7th Cir. 1995) (Posner, J.). And, of course, companies put in this position would be "at risk not just for potential liability but also for legal expenses. Even if the class certifications are later reversed, the defense costs and litigation fees for major class actions can run into the millions of dollars." Nancy Levit, *Megacases, Diversity, and the Elusive Goal of Workplace Reform*, 49 B.C. L. Rev. 367, 369 (Mar. 2008).

It is worth noting, too, that these class actions almost by definition would be brought in state court.

Unfortunately, that raises the stakes all the more because, as Congress has acknowledged, state court class action mechanisms tend to offer inferior procedural protections: "[O]ne reason for the dramatic explosion of class actions in state courts is that some state court judges are less careful than their federal court counterparts about applying the procedural requirements that govern class actions." S. Rep. No. 109-14, at 14. "In contrast, federal courts generally scrutinize proposed settlements much more carefully and pay closer attention to the procedural requirements for certifying a matter for class treatment." *Id.*

B. Increased Litigation Costs Would Divert Funds From Food Safety Programs And Could Raise Food Prices.

Ironically, an increase in food safety-related class action lawsuits also may undermine food company efforts to continually enhance food safety. Every company has finite resources, and a dollar devoted to litigation defense is a dollar that cannot be devoted to enhancing food safety.

Just as important, substantially higher food industry litigation costs are sure to translate down the line into higher food prices. That is not something amici ever desire, but it would be especially unfortunate in the current economic environment, when more and more Americans are having trouble paying for basic necessities. The Nation is currently undergoing its worst grocery inflation since the early 1990s, driven in part by higher costs for commodities like corn and wheat and in part by higher oil prices. *See* Andrew Martin & Michael M. Grynbaum, *Costs Surge for*

Stocking the Pantry, N.Y. Times, Mar. 15, 2008.[5] With grocery costs up more than five percent in the past year and staples like milk and cheese up more than 15 percent, *see id.*, nearly two in ten American families now report that they are having trouble paying for food. Kaiser Family Found., *Economic Problems Facing Families* at 1 (Apr. 2008).[6] Litigation and settlement expenses that line the pockets of class action attorneys certainly would not help the situation. The only winner would be the plaintiffs' bar.

C. Private Actions Would Undermine FDA's Well-Calibrated Enforcement Approach.

Recognizing a private right of action under the state law FDCA analogues would have yet another negative side effect: the impediment of effective food safety enforcement.

A key FDCA component is the discretion it grants FDA to *decline* to take enforcement action where a warning, or some other lesser sanction, would be more appropriate. 21 U.S.C. § 336. This discretion is important because the FDCA is a strict liability statute, *see United States* v. *Dotterweich*, 320 U.S. 277 (1943), and there are clearly some technical or first-time violations of the FDCA's many rules that are not deserving of sanctions, much less criminal penalties. FDA has long embraced this principle, issuing warning letters in cases where, for example,

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[5] *Available at* http://www.nytimes.com/2008/03/15/business/15consumer.html?_r=1&ref=business&oref=slogin.

[6] *Available at* http://www.kff.org/kaiserpolls/upload/ 7773.pdf.

a drugmaker failed to list a drug's risks in an online advertisement due to a technical error on a website,[7] or where distributors of cherries were making health claims the agency thought too aggressive.[8] In this way FDA can focus on what it deems to be major violations—those that are so important that they deserve immediate sanctions—while nudging companies to come up to speed on less crucial issues.

Private actions would undermine this FDA approach by making *every* technical FDCA violation within the ambit of Section 343-1, no matter how minor in the grand scheme, a potential source of liability. Not only would that distract FDA and the industry from addressing the agency's priority issues, but it also could ensnarl FDA in matters it would much prefer to bypass. It is likely, for example, that the agency would become enmeshed in factual disputes triggered by litigation, that it would be made a party to demands for confidential information, and that it would be called upon to resolve questions regarding the meaning of the FDCA and its own regulations. FDA thus would lose control over its own limited enforcement resources.[9]

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[7] *See* Reuters, *FDA objects to online ad for Pfizer's Viagra*, Apr. 21, 2008, *available at* http://www.reuters.com/article/PBLSHG/idUSN2143852320080421.

[8] *See* Matt Milkovich, *FDA: Companies Must Stop Promoting Health Benefits of Cherries on Labels*, The Fruit Growers News, Oct. 2005, *available at* http://www.fruitgrowersnews.com/pages/ arts.php?ns=215.

[9] *See* Gardiner Harris, *F.D.A. Chief Writes Congress for More Money*, N.Y. Times, May 14, 2008 (reporting that FDA's commissioner "has written Congress that the agency needs an immediate infusion of $275 million to ensure that imported

Likewise, private actions could limit FDA's ability to respond appropriately to scientific advances. Under the current regime, FDA can adopt interim approaches to changing technologies and can develop its regulatory framework over time. Private actions could truncate that evolutionary process and force the agency to make decisions before the scientific record is complete.

Private actions also could hinder FDA's own investigative processes by making it more difficult for the food industry to cooperate. Presumably, the discovery process in private lawsuits would grant plaintiffs access to records otherwise maintained as confidential by the government. A company would have good reason to fear full voluntary cooperation with FDA if it knew it were creating a record that class action counsel could seize upon to sue the company in search of a big payout.

D. Private Enforcement Is Not Needed To Protect Consumers.

Finally, it is important to note that FDCA private actions are not necessary for consumer protection. As even a quick glance at FDA's published weekly reports makes clear, FDA vigorously enforces the statute's provisions through warning letters, recall demands, and more aggressive sanctions where appropriate. *See, e.g.*, FDA Enforcement Report (Apr. 30, 2008) (listing numerous pages of recalls, field corrections, and other agency actions for a

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foods, drugs and medical devices are safe"), *available at* http://www.nytimes.com/2008/05/14/washington/14fda.html.

single seven-day period).[10] And of course, a consumer who is actually injured by a food product does not need a statutorily-based private right of action to obtain relief. Remedies for such injuries already exist under well-established tort law.

* * *

Private rights of action, in the final analysis, would weaken FDA while imposing heavy costs on food companies and, by extension, consumers. No doubt that is why Congress chose, when it enacted the FDCA, to limit FDCA enforcement power to government agents, *see Pacific Trading Co.* v. *Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976), to explicitly reject a private right of action, *see National Women's Health Network, Inc.* v. *A.H. Robins Co.*, 545 F. Supp. 1177, 1179-80 (D. Mass. 1982), and to bestow upon FDA the discretion to decide when an FDCA violation is worthy of sanctions, *see* 21 U.S.C. § 336. Amici agree with petitioners that it is implausible to conclude, as the California Supreme Court did, that Congress abandoned all three of those time-tested choices (1) without ever so much as suggesting that it planned to do so, and (2) by means of an amendment that did not purport to do so on its face. The Court should grant review to correct this error on an important question of federal law.

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[10] *Available at* http://www.fda.gov/bbs/topics/ENFORCE/2008/ENF01054.html.

CONCLUSION

For the foregoing reasons, and those in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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ALBERTSON'S, INC., et al.,

Petitioners,

v.

JENNIFER KANTER, et al.,

Respondents.

On Petition For A Writ Of Certiorari To The California Supreme Court

BRIEF OF REXALL SUNDOWN, INC., AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTRODUCTION AND INTEREST OF *AMICUS CURIAE*

Amicus curiae Rexall Sundown, Inc. ("Rexall Sundown") respectfully submits this brief in support of petitioners Albertson's, Inc., The Kroger Co., Safeway, Inc., and Bristol Farms, Inc.[1]

Rexall Sundown is a leader in the health products industry. It develops, manufactures, markets, and sells a broad line of vitamins, herbals, and nutritional supplements under various brand names. Rexall Sundown's products are sold in a variety of retail outlets throughout the United States, including mass merchandisers, drugstore chains, supermarkets, independent drugstores, and health food stores. Rexall Sundown's products are subject to labeling requirements established by the federal Food, Drug and, Cosmetic Act (FDCA), 21 U.S.C. § 301 (2008), et seq., and implementing regulations issued by the Food and Drug Administration (FDA).

Rexall Sundown is a defendant in a pending private California state court action entitled *Jarvis, et al. v. Royal Numico N.V., et al.,* California Superior

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[1] This brief is submitted with the written consent of counsel for all parties, who were timely notified pursuant to United States Supreme Court Rule 37.2(a) of the intention of *amicus* to file this brief. The brief was authored solely by *amicus* and its counsel. It was not authored in whole or in part by counsel for any party. No one other than *amicus* made any monetary contribution to the preparation or submission of this brief.

Court Case No. CGC-02-403532 ("*Jarvis*").[2] The complaint alleges that Rexall Sundown engaged in unfair competition in violation of California law by selling nutrition products bearing labels making various claims about the carbohydrate content of the products – for example, that the products are low in carbohydrates or "low carb" – that purportedly are unlawful under both the FDCA and California's state-law equivalent, or "little FDCA," the Sherman Food, Drug, and Cosmetic Law (Sherman Law), Cal. Health & Safety Code § 109875 et seq., which incorporates the provisions of the FDCA and its implementing regulations.

Rexall Sundown has asserted as a defense in *Jarvis* that the FDCA preempts the plaintiffs' claims. In the petitioners' case ("the *Farm Raised Salmon* case"), the California Supreme Court recognized that private state law actions, like *Jarvis*, seeking to enforce the FDCA conflict with the Congressional plan to vest FDCA enforcement exclusively with the FDA (and, in certain limited circumstances, with state governments as well). Therefore, the California Supreme Court acknowledged that the FDCA pre-empts such private FDCA enforcement actions. *See*

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[2] The other defendants in *Jarvis* are Rexall Sundown subsidiaries (Richardson Labs, Inc., MET-Rx USA, Inc., and Worldwide Sport Nutritional Supplements, Inc.), a former parent of Rexall Sundown (Royal Numico N.V.), a former Rexall Sundown sister company and retailer of Rexall Sundown products (General Nutrition Corporation), and a Rexall Sundown brand name (Low Glycemic Technologies, Inc.).

Pet. App. 11, 31-33. The California Supreme Court, however, also held that the FDCA does not bar similar private actions predicated on state laws like California's Sherman Law, which impose requirements identical to the FDCA. Pet. App. 3.

If the California Supreme Court's decision stands, it could impair Rexall Sundown's federal preemption defense to the claims asserted against it in the *Jarvis* matter based on alleged violations of California's Sherman Law. The *Jarvis* action, in fact, was stayed pending the California Supreme Court's decision in the *Farm Raised Salmon* case. Accordingly, the *Farm Raised Salmon* decision has a direct bearing on Rexall Sundown's interests.

The *Jarvis* case demonstrates how private "little FDCA" enforcement actions will impede the FDA's authority to make regulatory decisions based on the latest scientific knowledge available, and instead will leave such decisions to the whim of private litigants and their attorneys to determine when, who, and for what to sue without regard to the FDA's judgment. Although the FDA in the past has sent warning letters to Rexall Sundown subsidiaries and other companies raising objections to the use of terms such as "low carb," the FDA has since recognized that such carbohydrate content claims may be not only appropriate but also beneficial to consumers in light of recent scientific advances in the area of nutrition. For this reason, the FDA has announced that it will consider promulgating new regulations that will allow such carbohydrate content claims to appear on

food labels. In the interim, the FDA has exercised its discretion not to take any formal enforcement action against companies like Rexall Sundown that have used such terms to describe their products.

Permitting individuals to bring private actions alleging that carbohydrate content claims violate the requirements of state laws like California's Sherman Law, which are identical to the FDCA and its implementing regulations as they currently stand, will directly undermine the FDA's considered judgment concerning the propriety of carbohydrate content claims and how best to address them. More broadly, such private enforcement actions will subvert the federal policy to ensure that the FDA, and only the FDA, with its specialized knowledge and expertise, makes decisions based on the most current scientific developments about what nutritional information should be provided on food labels to best guide consumers.

The FDA's reconsideration of the propriety of carbohydrate content claims is not unique. Given developments in scientific knowledge about nutrition, the FDA frequently is required to reevaluate its regulations, or at least make informed decisions about when and how to enforce them, to best serve the overriding federal objectives to make available to consumers consistent nutrition information that can assist them in making healthier food choices, while at the same time "encourag[ing] product innovation through the development and marketing of nutritionally improved foods." Food Labeling: Nutrient

Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2302 (Jan. 6, 1993). While the FDA has the ability to ensure that *state governments* interpret, apply and enforce their state counterparts to the FDCA consistently with the FDA's decisions, the FDA has no such control over private parties and their attorneys. Therefore, and contrary to the decision of the California Supreme Court, private actions seeking to enforce state duplicates of the FDCA conflict with the FDA's regulatory mandate and should be precluded under the doctrine of conflict preemption, just as such actions are preempted when they attempt to enforce the FDCA itself.

It is for the FDA, not private litigants, to interpret FDCA regulations and decide when and how to apply them in light of the FDA's expertise in the areas it regulates. The California Supreme Court's decision allows private parties, who, unlike the FDA, do not represent the public interest, to usurp the FDA's authority so long as they do so pursuant to state duplicates of the FDCA and not the FDCA itself. But the California Supreme Court's distinction between allowing private parties to enforce the FDCA and allowing them to enforce its state-law duplicates is one without a difference. The interference with the FDA's ability to regulate consistently and appropriately in the field committed to its discretion is the same.

For these reasons, Rexall Sundown urges this Court to review and reverse the decision of the California Supreme Court in the *Farm Raised Salmon* case.

ARGUMENT

PRIVATE "LITTLE FDCA" ENFORCEMENT ACTIONS WILL USURP THE FDA'S EXCLUSIVE AUTHORITY TO REGULATE UNIFORMLY, AS ILLUSTRATED BY THE *JARVIS* CASE.

Because the *Jarvis* case provides a prime example of how private actions to enforce state counterparts of the FDCA will obstruct the FDA's regulatory authority, it is important to understand the details of the *Jarvis* case as well as the relevant regulatory framework established by the FDA. Accordingly, in the first section below, we outline the allegations of the *Jarvis* complaint. In the following two sections, we set forth the current applicable FDCA regulations, and the FDA's position on the enforcement of those regulations while the FDA reconsiders them in the face of advances in nutritional science. Finally, in the last section of this brief, we demonstrate that private "little FDCA" enforcement actions like *Jarvis* will compromise the FDA's regulatory decisions and interfere with its congressional mandate to ensure uniformity in food labeling in a manner that provides consumers with consistent and valuable nutrition information, but also encourages industry to develop

and market nutritional products that will appeal to the consuming public. *See* 58 Fed. Reg. at 2302.

A. The *Jarvis* Complaint Alleges That *Amicus* Rexall Sundown Violated California's Unfair Competition Law Because Its Product Labels Include Carbohydrate Content Claims That Allegedly Are Impermissible Under Both The FDCA And California's "Little FDCA," The Sherman Law.

The plaintiffs in *Jarvis* assert that *amicus* Rexall Sundown engaged in unfair competition in violation of California law, Bus. & Prof. Code § 17200, et seq., by marketing, distributing, and selling nutrition products – including bars, cookies, powders, and ready-to-drink mixes – whose packaging and labels state they are "Low Carb" or appropriate "For Low Carb Diets," signifying that the products are low in carbohydrates. The *Jarvis* plaintiffs also allege that Rexall Sundown improperly excluded from the "total carbohydrate" entry on the nutrition facts panel of its product labels ingredients, such as fiber, that do not have a significant impact on blood-sugar levels, and therefore typically do not count in low-carbohydrate diets. And the *Jarvis* plaintiffs allege that Rexall Sundown product labels improperly used the term "net carbs," which signifies the amount of carbohydrates of the type that impact blood-sugar levels, subtracting out ingredients that do not.

The *Jarvis* complaint alleges as a predicate to the unfair competition cause of action that these

carbohydrate content claims are not authorized by the FDCA or its implementing regulations, and therefore also violate California's Sherman Law, which provides that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the [FDCA] . . . shall be the food labeling regulations of this state." Cal. Health & Safety Code § 110100(a).

The *Jarvis* plaintiffs seek, among other things, a preliminary and permanent injunction prohibiting Rexall Sundown from continuing to make such allegedly improper carbohydrate content claims on its product labels, disgorgement of all funds Rexall Sundown acquired through the sale of products whose labels included the allegedly improper carbohydrate content claims, and attorneys' fees.

B. The FDCA And Its Implementing Regulations (And Therefore The Sherman Law) Presently Do Not Establish Definitions For Terms Such As "Low Carb" And "Net Carb."

In November 1990, the Nutrition Labeling and Education Act (NLEA) was signed into law, amending the FDCA. As the FDA has recognized, "the 1990 amendments [to the FDCA] ha[d] three basic objectives. . . . : (1) To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms

defined by [the FDA], and (3) to encourage product innovation through the development and marketing of nutritionally improved foods." 58 Fed. Reg. at 2302.

The FDCA, as amended by the NLEA, requires that all foods intended for human consumption (with limited exceptions not applicable here) bear labels indicating the amount of specified nutrients contained in the food, including the "total carbohydrates." 21 U.S.C. § 343(q)(1)(D) (2008). FDA regulations promulgated pursuant to the NLEA provide that "[t]otal carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the food." *See* 21 C.F.R. 101.9(c)(6) (2008). As such, the FDCA and its implementing regulations (and therefore the Sherman Law as well) presently do not expressly provide for the exclusion of ingredients that do not have a significant impact on blood-sugar levels from the "total carbohydrate" designation on food labels, even though due to their physiological impact the carbohydrates derived from these ingredients generally are irrelevant to carbohydrate-conscious consumers.

The FDCA, as amended by the NLEA, also provides that a food intended for human consumption is misbranded if it makes a claim on its label that expressly or implicitly characterizes the level of any nutrient required to be declared on the labeling (including carbohydrates), unless the claim uses a term that is defined in regulations promulgated by the FDA. 21 U.S.C. § 343(r)(1)(A), (2)(A) (2008).

To implement this portion of the NLEA, in 1993 the FDA published regulations that define and establish criteria for use of various descriptors, such as "free" and "low," for specified nutrients. *See* 58 Fed. Reg. at 2302; *see also, e.g.*, 21 C.F.R. 101.60(c)(1) (2008) (defining "sugar free"); 21 C.F.R. 101.62(b)(2) (2008) (defining "low fat"). At the time, however, the FDA did not define these terms for carbohydrates. *See* 58 Fed. Reg. at 2343. The FDA reasoned that "claims for specific amounts of carbohydrates . . . [cannot] be supported based on dietary recommendations in the major consensus reports because quantitative recommendations for carbohydrate consumption are not included." Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60453 (Nov. 27, 1991). Beyond that, the FDA had little reason to address carbohydrate content claims because, at the time of its rulemaking, consumer interest in carbohydrates was relatively low and such claims were rarely made on product labels.

C. The FDA Has Announced That It Will Reconsider Its Position On Carbohydrate Content Claims In Response To Recent Scientific Developments, And It Has Exercised Its Discretion In The Meantime Not To Take Formal Enforcement Actions With Respect To Such Claims.

Circumstances have changed dramatically since the FDA in 1993 determined how "total carbohydrate"

should be calculated and declined to define terms such as "low" with respect to carbohydrates. In the ensuing years, nutritional science has developed at a tremendous pace, challenging conventional diet wisdom. More definitive recommendations on carbohydrates have emerged, consumer interest in low-carbohydrate diets has surged while an obesity epidemic has swept the country, and carbohydrate-conscious products have been developed and marketed at a dizzying pace in response to escalating consumer demand. *See generally* Andrew Cooper, *Carbohydrate Nutrient Content Claims: Proposals for FDA Action and Lessons for Regulatory Response to Emerging Consumer Trends* (April 2006), at 1, 29, available at http://leda.law.harvard.edu/leda/data/763/Cooper06.pdf. The FDA has noted these developments and has responded accordingly.

On March 12, 2004, the FDA released a report by its Obesity Working Group, outlining the FDA's strategy to combat obesity in the United States. Among other things, the report recommended that the FDA implement uniform rules for carbohydrate labeling, including establishing an approved definition of "low carbohydrate" and providing guidance regarding "net carbohydrate" statements on product labels. *See* FDA OBESITY WORKING GROUP, CALORIES COUNT: REPORT OF THE WORKING GROUP ON OBESITY (2004), available at http://www.cfsan.fda.gov/~dms/owg-toc.html.

On the same day, the FDA published a Fact Sheet on Carbohydrates, which recognized that "in

response to consumer interest in popular low carbohydrate diets," many processed food manufacturers are making claims such as "low," "reduced," or "free" to describe the amount of carbohydrate in their products. *See FDA Fact Sheet on Carbohydrates* (Mar. 12, 2004), available at http://www.fda.gov/oc/initiatives/obesity/factsheet.html. The FDA noted that "[t]hese claims are nutrient content claims (i.e., they characterize the amount of a nutrient, carbohydrate, in a food) and must be made in accordance with an authorizing regulation," but that "[c]urrently, FDA's regulations do not define any term to describe the amount of carbohydrate in a food." *Id.* The FDA stated that it "intends to initiate rulemaking proceedings for nutrient content claims for carbohydrate. In addition, the agency intends to provide guidance to food manufacturers on the use of the term 'net' in relation to the carbohydrate content of food." *Id.*

In August 2004, Lester Crawford, the FDA's Acting Commissioner, reiterated that the FDA plans to "demystify carbohydrates" by "publishing a proposed rule and providing guidance regarding claims on the carbohydrate content of foods," including the use of terms such as "low carb" and "net carb." *See* Newsmaker Luncheon Speech by Lester M. Crawford, Acting Commissioner of the FDA (Aug. 2, 2004), available at http://www.fda.gov/oc/speeches/2004/newsmaker0802.html.

As promised, the FDA accepted and opened dockets during 2004 for several citizens' petitions (by both industry and consumer groups) which requested

the FDA to promulgate rules and guidelines regarding carbohydrate labeling, including claims such as "carbohydrate free," "low carbohydrate," "reduced carbohydrate," and "net carbohydrate." *See* FDA Docket Nos. 2204p-0105, 2004p-0107, 2004p-0110, 2004p-0297, 2004p-0298, 2004p-0299, 2004p-0473, and 2004p-0542, available at http://www.fda.gov/ohrms/dockets/default.htm (last visited May 12, 2008).

In April 2005, the FDA published a notice in the Federal Register announcing that the FDA was performing an experimental study on carbohydrate content claims on food labels. *See* Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Carbohydrate Content Claims on Food Labels, 70 Fed. Reg. 18032 (Apr. 8, 2005). In this notice, the FDA reiterated that current FDCA regulations make no provision for the use of nutrient content claims that characterize the level of carbohydrate in foods. *Id.* at 10833. The stated purpose of the study and data collection was "to help enhance FDA's understanding of consumer response to carbohydrate content claims on food labels." *Id.* The FDA stated that it planned to test different types of carbohydrate claims, including "carb free," "low carb," and "Xg net carbs" (where "X" is a number). *Id.*

In November 2007, the FDA published in the Federal Register an advance notice of proposed rulemaking to request comment on contemplated changes to regulations concerning nutrient labeling. *See* Food Labeling: Revision of Reference Values and

Mandatory Nutrients, 72 Fed. Reg. 62149 (Nov. 2, 2007). In this notice, the FDA stated that when it issued the existing nutrient labeling regulations in 1993, "it considered the diet and health information that was current at the time," but "[n]ew information has since become available" which has "stimulated extensive discussion in the scientific community." *Id.* at 62150. With respect to carbohydrates, in particular, the FDA referenced the pending citizens' petitions concerning carbohydrate content claims, and solicited comment on "what should be included or excluded in the current calculation of 'total carbohydrate,'" and whether carbohydrates should "be classified and declared in nutrition labeling based on their chemical definition or their physiological effect."[3] *Id.* at 62168 & n. 7, 62169.

Notably, although before 2004, the FDA issued warning letters to various companies, including *amicus* Rexall Sundown, concerning the use of claims such as "low carb" and the exclusion of "non-impact" carbohydrates from the calculation of the "total carbohydrates," the FDA has not taken any other enforcement action since accepting the petitions seeking new guidelines on carbohydrate labeling and beginning its study of the carbohydrate labeling issue. At the same time, the FDA has indicated

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[3] The FDA's website shows the petitions remain "pending" as of the filing of this *amicus* brief. *See* Chronological List of Petitions, available at http://www.fda.gov/ohrms/dockets/CITPETS/04citpetlist.htm.

informally that it essentially accepts the use of "net carbohydrate" claims. In a letter to the National Consumers League, Acting FDA Commissioner Crawford wrote that "although FDA has not issued guidance regarding the use of such statements, the agency has not generally objected to the use of 'net carbohydrate' type information on food labels if the label adequately explains how the terms are used so that it would not be false or misleading to consumers."[4] Letter from Lester M. Crawford, Acting Commissioner of Food and Drugs, FDA, to Linda F. Golodner, President, National Consumers League (Nov. 19, 2004) (No. 2004p-0105), available at http://www.fda.gov/ohrms/dockets/dockets/04p0105/04p-0105-ans00001-vol1.pdf; *see also* letter from Michael M. Landa, Deputy Director for Regulatory Affairs,

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[4] While the FDA considers the carbohydrate content labeling issue, the United States Department of Agriculture ("USDA") Food Safety and Inspection Service ("FSIS") has issued interim regulatory guidance to companies under its oversight concerning the proper use of carbohydrate content claims such as "Net Carbs," "Effective Carbs," and "Net Impact Carbs." *See* FSIS, Statement of Interim Policy on Carbohydrate Labeling Statements (Dec. 22, 2003), available at http://www.fsis.usda.gov/OPPDE/larc/Policies/CarbLabel.htm. The United States Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau ("TTB") has issued similar interim guidelines concerning permissible use of claims such as "low carbohydrate," "reduced (lower) carbohydrate," and "fewer carbohydrates." *See* TTB, Rul. 2004-1, Caloric and Carbohydrate Representations in the Labeling and Advertising of Wine, Distilled Spirits and Malt Beverages (Apr. 7, 2004), available at http://www.ttb.gov/rulings/2004-1.pdf.

Center for Food Safety and Applied Nutrition, FDA, to Nancy L. Schnell, Deputy General Counsel, Unilever United States, Inc. (Sept. 15, 2005) (No. 2004p-0298), available at http://www.fda.gov/ohrms/dockets/dockets/04p0298/04p-0298-ans0001-vol2.pdf.

D. The California Supreme Court's Decision In The *Farm Raised Salmon* Case Arguably Would Permit Private Actions To Enforce Restrictions On Carbohydrate Content Claims In State Duplicates Of The FDCA, Directly Conflicting with the FDA's Considered Decision Not To Pursue Such Enforcement Actions.

As explained, the FDA has recognized in the face of changing views in nutritional science that carbohydrate content claims may be both proper and helpful to consumers concerned about maintaining healthy diets. As a consequence, the FDA has exercised its congressionally-granted authority not to take formal enforcement actions against companies distributing products bearing these carbohydrate content claims while the FDA considers revising existing regulations accordingly. *See* 21 U.S.C. § 336 (2008) (granting the FDA the power not to prosecute "minor violations of [the FDCA] whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning"); *see also Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (recognizing that the FDCA's "enforcement provisions . . . commit complete discretion to [the FDA] to decide how and

when they should be exercised"). This Court has observed that "[t]his flexibility [concerning enforcement] is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001).

Despite the FDA's considered judgment, which this Court has recognized as vital to the accomplishment of federal objectives, the California Supreme Court's decision in the *Farm Raised Salmon* case arguably would permit private state-court actions, like the *Jarvis* case, to proceed so long as they are premised on purported violations of state-law duplicates of the FDCA, rather than the FDCA itself – even though the FDA has declined to pursue enforcement actions and is reconsidering the relevant regulations.[5]

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[5] It bears noting that the California Supreme Court was simply wrong in stating that "[n]o court, particularly after passage of the NLEA, has ever held that states may not provide a private remedy for the violation of state laws imposing requirements identical to those imposed by federal law" under the FDCA. Pet. App. 30. Both before and after passage of the NLEA, courts held precisely that. *See Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corporation*, 626 F. Supp. 278, 283 (D. Mass. 1986) (private claims seeking to enforce *both* the FDCA *and* "the Massachusetts statute which parallels the FDCA" were preempted by federal law); *Fraker v. KFC Corp.*, No. 06-CV-01284, 2007 WL 1296571, *4 (S.D. Cal. Apr. 30, 2007) ("to the extent Plaintiff contends that alleged violations of the FDCA *and [California's] Sherman Law* give rise to viable

(Continued on following page)

As the California Supreme Court observed, *state governments* may be able to prosecute under their state counterparts to the FDCA the very same purported violations concerning carbohydrate content claims that the FDA has declined to pursue pending its reconsideration of the relevant federal regulations. *See* Pet. App. 34. But the FDA has stated its intention "to work with the States to attempt to ensure that State provisions that are identical to provisions in the [FDCA] are interpreted by the States in a way that is as consistent as possible with the FDA's interpretation of the Federal provisions." 58 Fed. Reg. 2457, 2458 (Jan. 6, 1993). While the FDA has means at its disposal to prevent *state governments* from interfering with its enforcement decisions concerning carbohydrate content claims, it has no such control over private parties and their attorneys. The California Supreme Court's decision gives individuals carte blanche to override the FDA's judgment.

Other courts have recognized that it would undermine the FDA's regulatory authority to permit private parties to prosecute claims based on matters that the FDA has yet to resolve definitely. For example, in *Summit Technology, Inc. v. High-Line Medical Instruments Co., Inc.*, 922 F.Supp. 299 (C.D. Cal. 1996), the court considered a private Lanham Act claim arising from the defendants' allegedly unlawful

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[private] state law claims, such claims are impliedly preempted by the FDCA").

importation, promotion, and use of ophthalmological laser devices that were not approved by the FDA. The court noted:

> It is evident from the Complaint (and the accompanying exhibits) that the FDA is continuing to investigate whether Defendants have actually violated FDA regulations. . . . And, regardless of any warning letters that the FDA may have sent to Defendants, it is clear that the FDA has not completed this investigation. Indeed, after further review, the FDA *could* ultimately decide . . . that further approval procedures are unnecessary. Plaintiff's Lanham Act cause of action would thus "usurp[ ] the FDA's discretionary role in the application and interpretation of its regulations."

Id. at 306 (emphasis in original) (citations omitted) (quoting *Fender v. Medtronic, Inc.*, 887 F. Supp. 1326, 1332 (E.D. Cal. 1995)).[6]

Similarly, it is evident that, despite any warning letters it may have issued, the FDA is continuing to

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[6] In a subsequent order, the court reiterated: "Simply judging from the correspondence attached as exhibits to the Complaint, it is apparent that the FDA has not yet determined whether to take action against [Defendant] for its importation of [the devices]. In essence, the FDA has not yet determined how it will interpret and enforce its own regulations with regard to this question, and the Court must therefore decline to usurp the FDA's authority." *Summit Technology, Inc. v. High-Line Medical Instruments Co., Inc.*, 933 F. Supp. 918, 934 (C.D. Cal. 1996).

investigate whether carbohydrate content claims of the type at issue in *Jarvis* should be expressly permitted. A private action based on such carbohydrate content claims would usurp the FDA's discretionary role in the application and enforcement of its own regulations, regardless of whether the action is grounded in the FDCA or one of the FDCA's state equivalents.

Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222 (3d Cir. 1990), is also instructive. There, the Third Circuit addressed "the question whether a Lanham Act false labeling claim exists against a [cough syrup] manufacturer who lists an ingredient as 'inactive' when FDA standards seem to require that such an ingredient to be labeled as 'active.'" *Id.* at 230. Despite what FDA standards "seemed" to require, the FDA had not conclusively found that the ingredients in question had to be labeled "active." *Id.* The Third Circuit declined to recognize the Lanham Act claim, noting that such a claim would usurp the FDA's authority to interpret and enforce its own regulations. *Id.* at 231. The Third Circuit explained: "Because 'agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise.'" *Id.* (quoting *McKart v. United States*, 395 U.S. 185, 194 (1969)).

Significantly, the Third Circuit in *Sandoz* noted that the private plaintiff was "free to petition the FDA to investigate the[ ] alleged labeling violations"

and, in fact, the plaintiff "represent[ed] that it has embarked upon this path already." *Sandoz*, 902 F.2d at 231, n. 10. But the Third Circuit stated: "The fact that [the plaintiff] has been unable to get a quick response from the FDA . . . does not create a claim . . . under the Lanham Act." *Id.*

The same principle applies to carbohydrate content claims. The propriety of such claims is the subject of several FDA petitions that the FDA is in the process of considering. The FDA's inability yet to resolve the matter demonstrates the complexity of the issue, the need for the FDA to make a decision in a considered manner based on its specialized knowledge, after evaluating all the comments it has solicited, and the mischief that will ensue if private parties could jump ahead of the FDA's deliberative process.

Put simply, it is the FDA's province, not private litigants', to interpret relevant FDCA regulations and make decisions about when and how to apply them in light of the FDA's expertise in the areas it regulates. The California Supreme Court's decision ignores this, allowing private parties, who, unlike the FDA, do not represent the public interest, to usurp the FDA's authority so long as they do so pursuant to state duplicates of the FDCA and not the FDCA itself. That is a distinction without a difference. The deleterious effect on the FDA's ability to regulate consistently

and thoughtfully in the field committed to its discretion is exactly the same.

CONCLUSION

For the foregoing reasons, *amicus* Rexall Sundown respectfully requests that the Court grant the petition for certiorari.

Respectfully submitted,

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